

AMENDED IN SENATE APRIL 18, 2005

**SENATE BILL**

**No. 734**

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**Introduced by Senator Torlakson**

February 22, 2005

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An act to amend Sections 11159.2, 11161, 11161.5, 11162.1, 11165, and 11190 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 734, as amended, Torlakson. Controlled substances.

(1) Existing law provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill would impose these requirements on any prescription for a controlled substance for use by a patient who has a terminal illness.

(2) Existing law provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

This bill would require the court, in its order, to also prohibit the practitioner from obtaining, ordering, or using any additional prescription forms. The bill would impose a state-mandated local program by requiring the law enforcement agency obtaining the order to notify the Department of Justice of the order. The bill would make clarifying and conforming changes to this and related provisions.

(3) Existing law provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy; the board may approve security printer applications after the applicant has provided specified

information and the applicant's fingerprints, in a manner specified by the board, for the purpose of completing state and federal criminal background checks.

This bill would revise the latter provision to provide instead that the prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice and that the department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks. The bill would provide that the applicant shall submit his or her fingerprint images and related information to the department for the purpose of the department obtaining information as to the existence and nature of a record of specified state, federal, or foreign level convictions and arrests. Requests for federal level criminal offender record information received by the department shall be forwarded to the Federal Bureau of Investigation by the department. The bill would provide that the department shall assess the applicant a fee sufficient to cover all processing or maintenance costs of the department associated with providing the background checks, as specified.

(4) Existing law provides that the Board of Pharmacy or the Department of Justice may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime.

This bill would provide that the Department of Justice, but not the Board of Pharmacy, may deny the security printer application for the specified reasons, including if any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant who has direct access, management, or control of controlled substance prescription forms has been convicted of a crime. The bill would also add as a condition for approval as a security printer that the applicant authorize ~~the board or~~ department to make any examination of books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce the provisions relating to security printers. *An approved applicant would be required to submit an exemplar of a controlled substance prescription form, with all security features, to the department within 30 days of initial production.*

(5) Existing law provides that prescription forms shall be printed with specified features.

This bill would provide that prescription forms shall also include the feature of an identifying number assigned to the approved security printer by the Department of Justice. The bill would also require the forms to set forth specified information, as appropriate, with respect to ~~practitioners with privileges to prescribe scheduled controlled substances, physician assistants authorized to issue a drug order, and multiple prescribers.~~

(6) Existing law provides that with respect to specified controlled substances each dispensing pharmacy or prescriber shall provide specified information to the Department of Justice, as specified.

This bill would require the information from the dispensing pharmacy to include the method of payment for the prescription and the information from the dispensing prescriber to be provided to the department in a format set by the department *pursuant to regulation*.

(7) *Existing law provides for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.*

*This bill would provide that the Department of Justice shall, contingent upon the availability of adequate funds, evaluate the viability of implementing real time reporting, as defined, of controlled substances in the operation of CURES.*

(8) Existing law generally provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor, punishable as specified. This bill, to the extent it revises existing crimes, would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 11159.2 of the Health and Safety Code  
2 is amended to read:

3 11159.2. (a) Notwithstanding any other provision of law, a  
4 prescription for a controlled substance for use by a patient who  
5 has a terminal illness shall meet the following requirements:

6 (1) Contain the information specified in subdivision (a) of  
7 Section 11164.

8 (2) Indicate that the prescriber has certified that the patient is  
9 terminally ill by the words "11159.2 exemption."

10 (b) A pharmacist may fill a prescription pursuant to this  
11 section when there is a technical error in the certification  
12 required by paragraph (2) of subdivision (a), provided that he or  
13 she has personal knowledge of the patient's terminal illness, and  
14 subsequently returns the prescription to the prescriber for  
15 correction within 72 hours.

16 (c) For purposes of this section, "terminally ill" means a  
17 patient who meets all of the following conditions:

18 (1) In the reasonable medical judgment of the prescribing  
19 physician, the patient has been determined to be suffering from  
20 an illness that is incurable and irreversible.

21 (2) In the reasonable medical judgment of the prescribing  
22 physician, the patient's illness will, if the illness takes its normal  
23 course, bring about the death of the patient within a period of one  
24 year.

25 (3) The patient's treatment by the physician prescribing a  
26 Schedule II controlled substance pursuant to this section  
27 primarily is for the control of pain, symptom management, or  
28 both, rather than for cure of the illness.

29 (d) This section shall become operative on July 1, 2004.

30 SEC. 2. Section 11161 of the Health and Safety Code is  
31 amended to read:

32 11161. (a) When a practitioner is named in a warrant of  
33 arrest or is charged in an accusatory pleading with a felony  
34 violation of Section 11153, 11154, 11156, 11157, 11170, 11173,  
35 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5,

1 11379, 11379.5, or 11379.6, the court in which the accusatory  
2 pleading is filed or the magistrate who issued the warrant of  
3 arrest shall, upon the motion of a law enforcement agency which  
4 is supported by reasonable cause, issue an order which requires  
5 the practitioner to surrender to the clerk of the court all controlled  
6 substance prescription forms in the practitioner's possession at a  
7 time set in the order and which prohibits the practitioner from  
8 obtaining, ordering, or using any additional prescription forms.  
9 The law enforcement agency obtaining the order shall notify the  
10 Department of Justice of this order. Except as provided in  
11 subdivisions (b) and (e) of this section, the order shall remain in  
12 effect until further order of the court. Any practitioner possessing  
13 prescription forms in violation of the order is guilty of a  
14 misdemeanor.

15 (b) The order provided by subdivision (a) shall be vacated if  
16 the court or magistrate finds that the underlying violation or  
17 violations are not supported by reasonable cause at a hearing held  
18 within two court days after the practitioner files and personally  
19 serves upon the prosecuting attorney and the law enforcement  
20 agency that obtained the order, a notice of motion to vacate the  
21 order with any affidavits on which the practitioner relies. At the  
22 hearing, the burden of proof, by a preponderance of the evidence,  
23 is on the prosecution. Evidence presented at the hearing shall be  
24 limited to the warrant of arrest with supporting affidavits, the  
25 motion to require the defendant to surrender controlled substance  
26 prescription forms and to prohibit the defendant from obtaining,  
27 ordering, or using controlled substance prescription forms, with  
28 supporting affidavits, the sworn complaint together with any  
29 documents or reports incorporated by reference thereto which, if  
30 based on information and belief, state the basis for the  
31 information, or any other documents of similar reliability as well  
32 as affidavits and counter affidavits submitted by the prosecution  
33 and defense. Granting of the motion to vacate the order is no bar  
34 to prosecution of the alleged violation or violations.

35 (c) The defendant may elect to challenge the order issued  
36 under subdivision (a) at the preliminary examination. At that  
37 hearing, the evidence shall be limited to that set forth in  
38 subdivision (b) and any other evidence otherwise admissible at  
39 the preliminary examination.

1 (d) If the practitioner has not moved to vacate the order issued  
2 under subdivision (a) by the time of the preliminary examination  
3 and he or she is held to answer on the underlying violation or  
4 violations, the practitioner shall be precluded from afterwards  
5 moving to vacate the order. If the defendant is not held to answer  
6 on the underlying charge or charges at the conclusion of the  
7 preliminary examination, the order issued under subdivision (a)  
8 shall be vacated.

9 (e) Notwithstanding subdivision (d), any practitioner who is  
10 diverted pursuant to Chapter 2.5 (commencing with Section  
11 1000) of Title 7 of Part 2 of the Penal Code may file a motion to  
12 vacate the order issued under subdivision (a).

13 (f) This section shall become operative on November 1, 2004.

14 SEC. 3. Section 11161.5 of the Health and Safety Code is  
15 amended to read:

16 11161.5. (a) Prescription forms for controlled substance  
17 prescriptions shall be obtained from security printers approved  
18 by the Department of Justice.

19 (b) The department may approve security printer applications  
20 after the applicant has provided the following information:

21 (1) Name, address, and telephone number of the applicant.

22 (2) Policies and procedures of the applicant for verifying the  
23 identity of the prescriber ordering controlled substance  
24 prescription forms.

25 (3) Policies and procedures of the applicant for verifying  
26 delivery of controlled substance prescription forms to  
27 prescribers.

28 (4) (A) The location, names, and titles of the applicant's agent  
29 for service of process in this state; all principal corporate officers,  
30 if any; and all managing general partners, if any.

31 (B) A report containing this information shall be made on an  
32 annual basis and within 30 days after any change of office,  
33 principal corporate officers, or managing general partner.

34 (5) (A) A signed statement indicating whether the applicant,  
35 principal corporate officers, or managing general partners have  
36 ever been convicted of, or pled no contest to, a violation of any  
37 law of a foreign country, the United States, or any state, or of any  
38 local ordinance.

39 (B) The department shall provide the applicant with the means  
40 and direction to provide fingerprints and related information, in a

1 manner specified by the department, for the purpose of  
2 completing state, federal, or foreign criminal background checks.

3 (C) Any applicant described in subdivision (b) shall submit his  
4 or her fingerprint images and related information to the  
5 department, for the purpose of the department obtaining  
6 information as to the existence and nature of a record of state,  
7 federal, or foreign level convictions and state, federal, or foreign  
8 level arrests for which the department establishes that the  
9 applicant was released on bail or on his or her own recognizance  
10 pending trial, as described in subdivision (l) of Section 11105 of  
11 the Penal Code. Requests for federal level criminal offender  
12 record information received by the department pursuant to this  
13 section shall be forwarded to the Federal Bureau of Investigation  
14 by the department.

15 (D) The department shall assess against each applicant a fee  
16 determined by the department to be sufficient to cover all  
17 processing, maintenance, and investigative costs generated from  
18 or associated with completing state, federal, or foreign  
19 background checks pursuant to this section with respect to that  
20 applicant; the fee shall be paid by the applicant at the time he or  
21 she submits fingerprints and related information to the  
22 department.

23 (E) The department shall retain fingerprint impressions and  
24 related information for subsequent arrest notification pursuant to  
25 Section 11105.2 of the Penal Code for all applicants.

26 (c) The department may, within 60 calendar days of receipt of  
27 the application from the applicant, deny the security printer  
28 application.

29 (d) The department may deny a security printer application on  
30 any of the following grounds:

31 (1) The applicant, any individual owner, partner, corporate  
32 officer, manager, agent, representative, employee, or  
33 subcontractor for the applicant, who has direct access,  
34 management, or control of controlled substance prescription  
35 forms, has been convicted of a crime. A conviction within the  
36 meaning of this paragraph means a plea or verdict of guilty or a  
37 conviction following a plea of nolo contendere. Any action  
38 which a board is permitted to take following the establishment of  
39 a conviction may be taken when the time for appeal has elapsed,  
40 the judgment of conviction has been affirmed on appeal, or when

1 an order granting probation is made suspending the imposition of  
2 sentence, irrespective of a subsequent order under the provisions  
3 of Section 1203.4 of the Penal Code.

4 (2) The applicant committed any act involving dishonesty,  
5 fraud, or deceit with the intent to substantially benefit himself,  
6 herself, or another, or substantially injure another.

7 (3) The applicant committed any act that would constitute a  
8 violation of this division.

9 (4) The applicant knowingly made a false statement of fact  
10 required to be revealed in the application to produce controlled  
11 substance prescription forms.

12 (5) The department determines that the applicant failed to  
13 demonstrate adequate security procedures relating to the  
14 production and distribution of controlled substance prescription  
15 forms.

16 (6) The department determines that the applicant has  
17 submitted an incomplete application.

18 (7) As a condition for its approval as a security printer, an  
19 applicant shall authorize the ~~Board of Pharmacy or~~ Department  
20 of Justice to make any examination of the books and records of  
21 the applicant, or to visit and inspect the applicant during business  
22 hours, to the extent deemed necessary by the board or department  
23 to properly enforce this section.

24 (e) *An approved applicant shall submit an exemplar of a*  
25 *controlled substance prescription form, with all security features,*  
26 *to the Department of Justice within 30 days of initial production.*

27 (f) The department shall maintain a list of approved security  
28 printers and the department shall make this information available  
29 to prescribers and other appropriate government agencies,  
30 including the Board of Pharmacy.

31 ~~(f)~~

32 (g) Before printing any controlled substance prescription  
33 forms, a security printer shall verify with the appropriate  
34 licensing board that the prescriber possesses a license and current  
35 prescribing privileges which permits the prescribing of controlled  
36 substances.

37 ~~(g)~~

38 (h) Controlled substance prescription forms shall be provided  
39 directly to the prescriber either in person, by certified mail, or by



1 a means that requires a signature signifying receipt of the  
2 package and provision of that signature to the security printer.

3 ~~(h)~~

4 (i) Security printers shall retain ordering and delivery records  
5 in a readily retrievable manner for individual prescribers for three  
6 years.

7 ~~(i)~~

8 (j) Security printers shall produce ordering and delivery  
9 records upon request by an authorized officer of the law as  
10 defined in Section 4017 of the Business and Professions Code.

11 ~~(j)~~

12 (k) (1) The department may revoke its approval of a security  
13 printer for a violation of this division or action that would permit  
14 a denial pursuant to subdivision (d) of this section.

15 (2) When the department revokes its approval, it shall notify  
16 the appropriate licensing boards and remove the security printer  
17 from the list of approved security printers.

18 SEC. 4. Section 11162.1 of the Health and Safety Code is  
19 amended to read:

20 11162.1. (a) The prescription forms for controlled substances  
21 shall be printed with the following features:

22 (1) A latent, repetitive “void” pattern shall be printed across  
23 the entire front of the prescription blank; if a prescription is  
24 scanned or photocopied, the word “void” shall appear in a pattern  
25 across the entire front of the prescription.

26 (2) A watermark shall be printed on the backside of the  
27 prescription blank; the watermark shall consist of the words  
28 “California Security Prescription.”

29 (3) A chemical void protection that prevents alteration by  
30 chemical washing.

31 (4) A feature printed in thermo-chromic ink.

32 (5) An area of opaque writing so that the writing disappears if  
33 the prescription is lightened.

34 (6) A description of the security features included on each  
35 prescription form.

36 (7) (A) Six quantity check off boxes shall be printed on the  
37 form and the following quantities shall appear:

38 1-24

39 25-49

40 50-74

1 75-100

2 101-150

3 151 and over.

4 (B) In conjunction with the quantity boxes, a space shall be  
5 provided to designate the units referenced in the quantity boxes  
6 when the drug is not in tablet or capsule form.

7 (8) Prescription blanks shall contain a statement printed on the  
8 bottom of the prescription blank that the "Prescription is void if  
9 the number of drugs prescribed is not noted."

10 (9) ~~(A)~~ The preprinted name, category of licensure, license  
11 number, federal controlled substance registration number of the  
12 prescribing practitioner.

13 ~~(B) The privileges of a practitioner to prescribe any of the~~  
14 ~~following controlled substances shall be preprinted beside the~~  
15 ~~prescriber's name and as designated in the prescriber's certificate~~  
16 ~~issued by the federal Drug and Enforcement Agency:~~

17 ~~(i) Schedule II narcotic;~~

18 ~~(ii) Schedule II nonnarcotic;~~

19 ~~(iii) Schedule III narcotic;~~

20 ~~(iv) Schedule III nonnarcotic;~~

21 ~~(v) Schedule IV;~~

22 ~~(vi) Schedule V.~~

23 (10) A check box indicating the prescriber's order not to  
24 substitute.

25 (11) An identifying number assigned to the approved security  
26 printer by the Department of Justice.

27 ~~(12) A physician assistant authorized by Section 3502.1 of the~~  
28 ~~Business and Professions Code to issue a drug order may do so~~  
29 ~~under his or her own name on prescription forms preprinted with~~  
30 ~~the information required by Section 11162 that are in compliance~~  
31 ~~with subdivision (d) of Section 3502.1 of the Business and~~  
32 ~~Professions Code.~~

33 (b) Each batch of controlled substance prescription forms shall  
34 have the lot number printed on the form and each form within  
35 that batch shall be numbered sequentially beginning with the  
36 numeral one.

37 (c) (1) A prescriber designated by a licensed health care  
38 facility may order controlled substance prescription forms for use  
39 by prescribers when treating patients in that facility without the

1 information required in paragraph (9) of subdivision (a) *or*  
2 *paragraph (3) of this subdivision.*

3 (2) Forms ordered pursuant to this subdivision shall have the  
4 name, category of licensure, license number, and federal  
5 controlled substance registration number of the designated  
6 prescriber and the name, address, category of licensure, and  
7 license number of the licensed health care facility preprinted on  
8 the form.

9 (3) (A) Forms ordered pursuant to this subdivision that list  
10 multiple prescribers on one prescription form shall have a check  
11 box by the name of each designated prescriber.

12 (B) Each designated prescriber who signs the prescription  
13 form shall identify himself or herself as the prescriber by  
14 checking the box by the prescriber's name.

15 (4) Forms ordered pursuant to this section shall not be valid  
16 prescriptions without the name, category of licensure, license  
17 number, and federal controlled substance registration number of  
18 the prescriber on the form.

19 (5) (A) The designated prescriber shall maintain a record of  
20 the prescribers to whom controlled substance prescription forms  
21 are issued.

22 (B) The record shall include the name, category of licensure,  
23 license number, federal controlled substance registration number,  
24 and the quantity of controlled substance prescription forms  
25 issued to each prescriber; the record shall be maintained in the  
26 health facility for three years.

27 (d) This section shall become operative on July 1, 2004.

28 SEC. 5. Section 11165 of the Health and Safety Code is  
29 amended to read:

30 11165. (a) To assist law enforcement and regulatory agencies  
31 in their efforts to control the diversion and resultant abuse of  
32 Schedule II and Schedule III controlled substances, and for  
33 statistical analysis, education, and research, the Department of  
34 Justice shall, contingent upon the availability of adequate funds  
35 from the Contingent Fund of the Medical Board of California, the  
36 Pharmacy Board Contingent Fund, the State Dentistry Fund, the  
37 Board of Registered Nursing Fund, and the Osteopathic Medical  
38 Board of California Contingent Fund, maintain the Controlled  
39 Substance Utilization Review and Evaluation System (CURES)  
40 for the electronic monitoring of the prescribing and dispensing of

1 Schedule II and Schedule III controlled substances by all  
2 practitioners authorized to prescribe or dispense these controlled  
3 substances.

4 (b) The reporting of Schedule III controlled substance  
5 prescriptions to CURES shall be contingent upon the availability  
6 of adequate funds from the Department of Justice. The  
7 Department of Justice may seek and use grant funds to pay the  
8 costs incurred from the reporting of controlled substance  
9 prescriptions to CURES. Funds shall not be appropriated from  
10 the Contingent Fund of the Medical Board of California, the  
11 Pharmacy Board Contingent Fund, the State Dentistry Fund, the  
12 Board of Registered Nursing Fund, or the Osteopathic Medical  
13 Board of California Contingent Fund to pay the costs of reporting  
14 Schedule III controlled substance prescriptions to CURES.

15 (c) CURES shall operate under existing provisions of law to  
16 safeguard the privacy and confidentiality of patients. Data  
17 obtained from CURES shall only be provided to appropriate  
18 state, local, and federal persons or public agencies for  
19 disciplinary, civil, or criminal purposes and to other agencies or  
20 entities, as determined by the Department of Justice, for the  
21 purpose of educating practitioners and others in lieu of  
22 disciplinary, civil, or criminal actions. Data may be provided to  
23 public or private entities, as approved by the Department of  
24 Justice, for educational, peer review, statistical, or research  
25 purposes, provided that patient information, including any  
26 information that may identify the patient, is not compromised.  
27 Further, data disclosed to any individual or agency as described  
28 in this subdivision shall not be disclosed, sold, or transferred to  
29 any third party.

30 (d) For each prescription for a Schedule II or Schedule III  
31 controlled substance, the dispensing pharmacy shall provide the  
32 following information to the Department of Justice in a  
33 frequency and format specified by the Department of Justice:

34 (1) Full name, address, gender, and date of birth of the patient.

35 (2) The prescriber's category of licensure and license number;  
36 federal controlled substance registration number; and the state  
37 medical license number of any prescriber using the federal  
38 controlled substance registration number of a  
39 government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

~~(9) Method of payment for prescription.~~

*(e) (1) The Department of Justice shall, contingent upon the availability of adequate funds, evaluate the viability of implementing real time reporting of controlled substances in the operation of CURES.*

*(2) For the purposes of this subdivision, "real time reporting" means \_\_\_\_.*

*(f) This section shall become operative on January 1, 2005.*

SEC. 6. Section 11190 of the Health and Safety Code is amended to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

1 (C) NDC (National Drug Code) number of the controlled  
2 substance dispensed.

3 (D) Quantity of the controlled substance dispensed.

4 (E) ICD-9 (diagnosis code), if available.

5 (F) Date of dispensing of the prescription.

6 (2) Each prescriber that dispenses controlled substances shall  
7 provide the Department of Justice the information required by  
8 this subdivision on a monthly basis in a format set by the  
9 Department of Justice *pursuant to regulation*.

10 (d) This section shall become operative on January 1, 2005.

11 SEC. 7. No reimbursement is required by this act pursuant to  
12 Section 6 of Article XIII B of the California Constitution for  
13 certain costs that may be incurred by a local agency or school  
14 district because, in that regard, this act creates a new crime or  
15 infraction, eliminates a crime or infraction, or changes the  
16 penalty for a crime or infraction, within the meaning of Section  
17 17556 of the Government Code, or changes the definition of a  
18 crime within the meaning of Section 6 of Article XIII B of the  
19 California Constitution.

20 However, if the Commission on State Mandates determines  
21 that this act contains other costs mandated by the state,  
22 reimbursement to local agencies and school districts for those  
23 costs shall be made pursuant to Part 7 (commencing with Section  
24 17500) of Division 4 of Title 2 of the Government Code.



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: SB 734**

**VERSION: AMENDED APRIL 18, 2005**

**AUTHOR: TORLAKSON**

**SPONSOR: DEPARTMENT OF JUSTICE**

**RECOMMENDED POSITION: OPPOSE UNLESS AMENDED**

**SUBJECT: CONTROLLED SUBSTANCES**

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### **Existing Law:**

1. Provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements. (H&S 11159.2)
2. Provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order. (H&S 11161)
3. Provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the board; the board may approve security printer applications after the board has completed a state and federal criminal background check. (H&S 11161.5)
4. Provides that the board or the Department of Justice (DOJ) may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime. (H&S 11161.5)
5. Provides that prescription forms shall be printed with specified features. (H&S 11162.1)
6. Provides that with respect to specified controlled substances each dispensing pharmacy or prescriber shall provide specified information to the Department of Justice, as specified. (H&S 11190)

### **This Bill:**

This bill would make several changes to facilitate the operation of Controlled Substances Utilization Review and Utilization Review and Evaluation System (CURES) and to allow for consistency with existing DOJ policy and practice and conformity with "best practices" model to prevent diversion of controlled substances. The bill would make the following changes:

1. Transfers responsibility from the board to DOJ to control the manner in which fingerprints are provided when conducting criminal background investigations of vendors applying to print security prescription forms.
  - a. Allows DOJ to collect fees.
  - b. Extends from 30 days to 60 days the period with which DOJ may deny an application.

- c. Allows DOJ to retain fingerprint impressions for subsequent enforcement and arrest.
- d. Allows DOJ to examine the books of security printers.

(H&S 11161.5 Amended)

2. Allows the terminally ill exemption (allowing a prescriber to use nonsecurity forms) for any controlled substance prescription. (Current law designates only C II drugs can be prescribed in this manner.) (H&S 11159.2 Amended)

3. Authorizes the Superior Court to order a prescriber not to order, obtain, or use any prescription forms during a pending criminal action. (H&S 11161 Amended)

4. Clarifies that DOJ is solely responsible for determining whether security printer applications are complete, for maintaining a list of approved security printers, and for revoking approval of security printers. (H&S 11161.5 Amended)

5. Clarifies how prescribers and physician assistants can state number of prescriptions included on form and otherwise comply with CURES program. (H&S 11162.1 Amended)

6. Requires approved security printers to print forms with a vendor identification code issued by the DOJ. (H&S 11162.1 Amended)

7. Requires the DOJ, when are available, to evaluate the viability of implementing real time reporting to CURES. (H&S 11165 Amended)

8. Requires direct dispensers of controlled substances to submit information to the DOJ in a format specified by the DOJ. (H&S 11190 Amended)

9. Makes other technical changes to allow for consistency with existing DOJ policy and practice.

### **Comment:**

**1) Author's Intent.** The bill is sponsored the DOJ. The author's intent is to make technical and clean-up changes to facilitate the effective operation of the CURES and the program duties of the Bureau of Narcotics Enforcement. Additionally, this bill would make technical changes to be consistent with existing DOJ policy and practice and conform to their "best practices" model to prevent diversion of controlled substances.

**2) Above and Beyond Current Requirements:** Provisions in AB 734 go beyond transferring oversight of the security printer program from the board to DOJ. In many cases the new requirements seem excessive. New provisions would:

a. Expand DOJ authority to:

- i. Retain the figure prints of applicants.
- ii. Extend the time to review security printer applications from 30 to 60 days.
- iii. Deny an application for a security printer if an applicant is found to have been convicted of a crime or if the applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime.
- iv. Inspect a security printer's business, or examine books and records anytime during regular business hours.



- b. Expand information required on prescription forms to include the identification number of security printer.

This bill expands and alters the components required on a security form. It expands the information pharmacies must submit to CURES.

The board submitted a modification to section 11165 to cap the board's funding to CURES at the amount approved by the Governor and the Legislature. This amendment needs to be included in the bill. (See attached.)

**3) Proposed Amendment.** Add a provision that would effectively cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ.

**4) Previous Legislation.** SB 151 (Burton, 2003, Chapter 406) implementing the "Pain Treatment and Diversion Act of 2003," the Controlled Substances Utilization Review and Evaluation System (CURES) became permanent.

**5) Support / Opposition.**

Support: Attorney General Bill Lockyer (sponsor)

Opposition: California Medical Association

**6) History.**

2005

July 6	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 12. Noes 1.) Re-referred to Com. on APPR.
June 30	Re-referred to Com. on HEALTH.
June 29	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 5. Noes 1.) Re-referred to Com. on APPR.
June 13	To Coms. on PUB. S. and HEALTH
May 26	In Assembly. Read first time. Held at Desk.
May 26	Read third time. Passed. (Ayes 25. Noes 9. Page 1174.) To Assembly.
Apr. 18	Set for hearing April 26.
Apr. 18	Read second time. Amended. Re-referred to Com. on PUB. S.
Apr. 14	From committee: Do pass as amended, but first amend, and re-refer to Com. on PUB. S. (Ayes 6. Noes 0.)
Apr. 6	Set for hearing April 13.
Apr. 4	Set, first hearing. Hearing canceled at the request of author.
Mar. 16	Set for hearing April 6.
Mar. 10	To Coms. on HEALTH and PUB. S.
Feb. 23	From print. May be acted upon on or after March 25.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

**SB 734: Proposed Amendments to CURES Statutory  
Provisions for Budgetary Issues**

SECTION 1. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds appropriations from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Payment from any of the above special funds for costs that exceed budgeted amounts is contingent upon receiving appropriation augmentations sufficient to cover the full costs billed by the Department of Justice.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number;  
federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

## **SB 734**

**As Amended: April 18, 2005**

### **ASSEMBLY COMMITTEE ON PUBLIC SAFETY**

Mark Leno, Chair

#### **SB 734 (Torlakson) -**

**SUMMARY :** Makes various technical and clarifying changes to the Controlled Substance Utilization Review and Evaluation System (CURES). Specifically, this bill :

- 1) Removes the reference to Schedule II controlled substances in Health and Safety Code Section 11159.2 to ensure that terminally ill patients can receive a prescription for illnesses, such as cancer or HIV, that contain not only Schedule II drugs but also compounds or combinations from all schedules, which can be written on the same prescription. This will ensure pharmacists will fill such prescriptions without disruption.
- 2) Authorizes the superior court to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action and requires the law enforcement agency obtaining such an order to notify the Department of Justice (DOJ).
- 3) Specifies that DOJ, and not the Board of Pharmacy, will control the manner in which fingerprints are provided.
- 4) Allows DOJ to collect a fee for processing criminal background checks when a vendor applies to become an approved security printer of prescription forms. Each applicant shall pay, at the time of filing an application for a permit, a fee determined by DOJ that will not exceed the application processing costs of DOJ.
- 5) Specifies and defines the security printer applicant class that must submit criminal background checks as any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms.
- 6) Authorizes DOJ to examine the books and records of any applicant or visit and inspect a certified security printer.
- 7) Directs security prescription form printers to submit a sample of their secure prescription forms to DOJ.

- 8) Requires an approved security printer to print their security prescription forms with a vendor identification code issued by DOJ.
- 9) Requires a check box by the name of each prescriber on a security prescription form to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form.
- 10) Allows a prescriber designated by a license health care facility, licensed clinic or other clinic exempt from licensure to order controlled substance prescription forms for use by prescribers when treating patients in that facility. This would also allow the licensed clinic or clinic exempt from licensure to avoid specified printing requirements that appear on the security prescription form.
- 11) Requires a designated prescriber to meet the requirements adding licensed clinic or clinic exempt from licensure pursuant to Health and Safety Code 1206 preprinted on the form.
- 12) Clarifies, by striking out text and allowing for a simple pre-printed statement on the bottom of prescription blanks that "prescription is void if the number of drugs is not noted."
- 13) Requires a prescriber who directly dispenses controlled substances to submit the information to DOJ in a format set by DOJ pursuant to regulation.

#### EXISTING LAW :

- 1) Establishes CURES for the electronic monitoring by DOJ of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these substances. (Health and Safety Code Section 11165.)
- 2) Requires that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order. (Health and Safety Code Section 11161.)
- 3) Provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy. The Board of Pharmacy may approve security printer applications after the applicant has

provided specific information and fingerprints, in a manner specified by the Board. The required information is used for the purpose of completing state and federal criminal background checks. (Health and Safety Code Section 11161.5.)

4)Provides that the Board of Pharmacy or DOJ may deny a security printer application for specific reasons, including where the applicant has been convicted of a crime. (Health and Safety Code Section 11161.5.)

5)Provides that prescription forms shall be printed with specific features. (Health and Safety Code Section 11162.1.)

6)Provides that with respect to specific controlled substances, each dispensing pharmacy or prescriber shall provide specific information to DOJ. [Health and Safety Code Section 11165(d).]

7)Provides that a violation of the provisions relating to the prescription of controlled substances is an alternate misdemeanor/felony. (Health and Safety Code Section 11153.)

8)States a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements. (Health and Safety Code Section 11159.2.)

FISCAL EFFECT : Unknown

COMMENTS :

1)Author's Statement : According to the author, "This bill makes technical and clean up changes to the law governing the CURES program in order to facilitate the effective operation of CURES and the program duties of DOJ's Bureau of Narcotics Enforcement."

2)Senate Health Committee : The Senate Health Committee analysis of this bill contains the following background information, "Under existing federal and state laws, controlled substances are ranked according to their potential for abuse, accepted medical use, and safety under medical supervision. Schedule I substances (e.g., heroin and LSD) have high potential for abuse, no currently accepted medical use, and lack accepted safety for use. Schedule II drugs (e.g., morphine, codeine, Demerol, and Percodan) have a high potential for abuse and high potential for physical or psychological dependence if used improperly, but have accepted medical value in treating pain.

"Schedule III drugs (e.g., Vicodin, anabolic steroids, codeine

with aspirin or Tylenol), Schedule IV drugs (e.g., Darvon, Valium, Halcyon, and Xanax), and Schedule V drugs (over-the-counter cough medicines with codeine) generally have less potential for abuse than Schedule I or II drugs, have accepted medical use in treatment, and lower potential for physical or psychological dependence.

"The Bureau of Narcotic Enforcement within DOJ currently administers and enforces the multiple-copy prescription surveillance program and is responsible for all state-controlled substance enforcement activities.

"The CURES program was established in 1997 by AB 3042 (Takasugi) in response to recommendations of the Controlled Substance Prescription Advisory Council established by SCR 74 in 1992. The purpose of CURES was to provide for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances. CURES provides for the electronic transmission of Schedule II prescription data to DOJ at the time prescriptions are dispensed.

"CURES was established as a three-year pilot project, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies of the two systems. Subsequent legislation extended the sunset on the program to July 1, 2008. A report to the Legislature by DOJ and the Board of Pharmacy in 1999 recommended that CURES be made a permanent program.

"According to the sponsor, the Attorney General, this bill addresses needed technical and administrative changes to existing state law. DOJ sponsors these changes to assist in the permanent operation of CURES within the CURES program. The changes remove inconsistencies within SB 151 and provide that DOJ policy and practice will conform with the 'best practices' model to prevent diversion of controlled substances.

"SB151 brought forth significant changes to the CURES program. One of the major changes was the elimination of the 65-year-old triplicate prescription form. The form was replaced with a new secure, tamper-resistant prescription form for Schedules II through IV controlled substances. In addition, CURES was also authorized to collect Schedule III prescription information.

"This bill attempts to amend several sections of the Health and Safety Code as it relates to controlled substances, the facilitation of the ongoing operation of CURES, and continued efforts by law enforcement in preventing the diversion and abuse of prescription drugs."

3)Arguments in Support : According to the Office of the Attorney General, "This bill makes technical changes to facilitate the operation of CURES and to clarify the program duties of the Bureau of Narcotics Enforcement and Board of Pharmacy. . . . This bill would make several changes to conform with the 'best practices' model to prevent diversion of controlled substances. . . . In addition, this bill makes other technical changes to allow for consistency with existing DOJ policy and practice. . . . Finally, this bill will allow for prescriptions from all schedules of drugs to be included on the same prescription form, and will require direct dispensers of controlled substances to submit information to the DOJ in a format to be developed by the DOJ."

4)Arguments Regarding Still Existing Problems With CURES : According to the California Medical Association, "Amendments must be adopted that will allow residents, interns, and fellows who do not have the ability to provide all information required on the security prescription pads to continue to prescribe as allowed by law and their respective training programs. . . . Further, amendments must be adopted to address the filling of faxed prescriptions."

#### REGISTERED SUPPORT / OPPOSITION :

##### Support

Office of the Attorney General (Sponsor)  
California Medical Association (Support if amended)

##### Opposition

California State Board of Pharmacy (Oppose unless amended)

Analysis Prepared by : Heather Hopkins / PUB. S. / (916)  
319-3744

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# **Attachment 5**

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AMENDED IN SENATE JUNE 15, 2005

AMENDED IN ASSEMBLY APRIL 13, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

## ASSEMBLY BILL

No. 21

Introduced by Assembly Member Levine

(Coauthors: Assembly Members Berg, Chavez, Cohn, De La Torre, Evans, Goldberg, Jones, Koretz, Laird, Lieber, Montanez, Nava, and Ruskin)

December 6, 2004

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An act to add ~~Section 4069~~ Sections 4069 and 4316 to the Business and Professions Code, relating to pharmacy.

### LEGISLATIVE COUNSEL'S DIGEST

AB 21, as amended, Levine. Pharmacists: ~~dispensing~~ *practice* requirements.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of that law a crime *and subject to the assessment of a fine by the board*. Under existing law, a prescription may be lawfully dispensed only by a pharmacist, unless otherwise specified by the Pharmacy Law.

This bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of ~~its~~ *those* provisions unprofessional conduct *and would also make harassment, as specified,*

of a patient by a pharmacist unprofessional conduct, subject to disciplinary action by the board.

Because the bill would specify an additional requirement violations under the Pharmacy Law, a violation of which would be punishable as a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1     SECTION 1. This act shall be known and may be cited as the  
2     Women's Contraceptive and Pharmaceutical Freedom Act of  
3     2005.

4     ~~SECTION 1.—~~

5     SEC. 2. Section 4069 is added to the Business and  
6     Professions Code, to read:

7     4069. (a) Notwithstanding any other provision of law, a  
8     pharmacist shall dispense a lawful prescription unless one of the  
9     following circumstances exists:

10    (1) The pharmacist determines, based on his or her  
11    professional training and judgment, that dispensing the  
12    prescription is contrary to law or, after consulting with the  
13    patient's prescriber, that it is contraindicated for the patient.

14    (2) The pharmacy does not have the prescribed trade or brand  
15    name drug in stock. The pharmacist shall offer the patient  
16    another drug product, if available, with the same active chemical  
17    ingredients of the same strength, quantity, and dosage form and  
18    of the same generic drug name, as determined by the United  
19    States Adopted Names and accepted by the federal Food and  
20    Drug Administration, as the prescribed drug product and follow  
21    the procedure or protocol described in Section 4073.

22    (3) (A) The pharmacist elects to refuse on ethical, moral, or  
23    religious grounds to dispense a drug pursuant to a lawful request.  
24    A pharmacist may decline to dispense a drug on these grounds

1 only after notifying his or her employer in writing of his or her  
2 objections. The pharmacist shall provide this notification upon  
3 acceptance of employment and immediately after any change to  
4 that decision.

5 (B) An employer shall, upon receipt of the notification  
6 described in subparagraph (A), establish a policy and protocol to  
7 accommodate the patient's ~~needs~~ *need* for the drug.

8 (b) An employer shall not withdraw an offer of employment or  
9 terminate employment based on the notification or change in the  
10 notification, as described in subparagraph (A) of paragraph (3) of  
11 subdivision (a).

12 (c) A violation of this section by a pharmacist constitutes  
13 unprofessional conduct for the purposes of Section 4301, subject  
14 to disciplinary action by the board.

15 *SEC. 3. Section 4316 is added to the Business and*  
16 *Professions Code, to read:*

17 *4316. It shall constitute unprofessional conduct and a*  
18 *violation of this chapter for a pharmacist to harass a patient by*  
19 *engaging in extreme or outrageous conduct and intentionally*  
20 *causing the patient emotional distress or by engaging in conduct*  
21 *with reckless indifference to the likelihood of causing the patient*  
22 *emotional distress. For these purposes, the emotional distress*  
23 *shall be actual and severe as determined by a reasonable person.*

24 ~~SEC. 2.—~~

25 *SEC. 4.* No reimbursement is required by this act pursuant to  
26 Section 6 of Article XIII B of the California Constitution because  
27 the only costs that may be incurred by a local agency or school  
28 district will be incurred because this act creates a new crime or  
29 infraction, eliminates a crime or infraction, or changes the  
30 penalty for a crime or infraction, within the meaning of Section  
31 17556 of the Government Code, or changes the definition of a  
32 crime within the meaning of Section 6 of Article XIII B of the  
33 California Constitution.

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# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 21**

**VERSION: AMENDED JUNE 15, 2005**

**AUTHOR: LEVINE**

**SPONSOR: LEVINE**

**RECOMMENDED POSITION: OPPOSE**

**SUBJECT: PHARMACISTS: PRACTICE REQUIREMENTS**

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### **Existing Law:**

- 1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052(8))
- 2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)
- 3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)
- 4) Requires the board to take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. (B&P 4301)

### **This Bill:**

- 1) Establishes the Women's Contraceptive and Pharmaceutical Freedom Act of 2005. (B&P 4069 Added)
- 2) States that it shall constitute unprofessional conduct and a violation of this chapter for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress. For these purposes, the emotional distress shall be actual and severe as determined by a reasonable person. (B&P 4316 Added)
- 3) Requires a violation of this section by a pharmacist to constitute unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board. (B&P 4069 Added)
- 4) Requires a pharmacist to dispense a "lawful" prescription unless one of the following circumstances exists:
  - a. The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient.
  - b. The pharmacy does not have the prescribed trade or brand name drug in stock. The pharmacist shall offer the patient another drug product, if available, with the same active

chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as the prescribed drug product and follow the procedure or protocol described in Section 4073.

- c. The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request.
  - i. A pharmacist may decline to dispense a drug on these grounds only after notifying his or her employer in writing of his or her objections.
  - ii. The pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

(B&P 4069 Added)

5) Requires an employer, upon receipt of a pharmacist objections, to establish a policy and protocol to accommodate the patient's need for the drug. (B&P 4069 Added)

6) Does not permit an employer to withdraw an offer of employment or terminate employment based on the notification or change in the notification. (B&P 4069 Added)

### **Comment:**

**1) Author's Intent.** The author's intent is to insure that pharmacists do not refuse to dispense EC to patients.

**2) In the News.** The issue on whether or not a pharmacist has a right to refuse to fill a prescription has been debated in the news and in state legislatures over the last year. The Washington Post reports that twelve states either have laws or are considering laws that would allow a pharmacist not to fill a prescription. While much of the debate has centered on birth control and EC, there are increasing news reports and web postings that indicate this issue is likely to expand into other moral issues such as assisted suicide, sterile needle programs, and pain management.

**3) Emotional Distress.** AB 21 adds an emotional distress provision to pharmacy law. Emotional distress provisions are not uncommon in professions law such as those governing Marriage and Family Therapists, Licensed Vocational Nurses, and Licensed Clinical Social Workers, where a licensee has the power to misuse their position and inflict emotional distress on a patient. The practice of pharmacy differs from other professions where a pharmacist interacts with a wide range of patients and customers. Some of these patients are on medications that may alter their perception of reality and others may be addicted to some medications and seeking to get more medications illegally. It is up to a pharmacist to use his or her best professional judgment under the law to either dispense or refuse to dispense a medication. Some patients may misinterpret a pharmacist's use of their judgment as causing emotional distress. In this situation, under the provision in AB 21 the patient can file a claim with the board claiming a pharmacist has misused their position. The board believes that it currently has the powers it needs to take enforcement action against a pharmacist that misuses their position and the addition of an emotional distress provision to pharmacy law is unnecessary.

**4) Enforcement.** Enforcement of AB 21 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacist's refusal to dispense EC. The June 15<sup>th</sup> amendments regarding unprofessional conduct and emotional distress may be difficult to enforce. If AB 21 is enacted the board anticipates that it will need to train its inspectors on the nuances of the law governing emotional distress.



**5) Legislative History.** Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

**6) Related Legislation.** SB 644 (Ortiz 2005) Dispensing Prescription Drugs And Devices, would require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. SB 644 is awaiting hearing in the Assembly Health Committee.

**7) Federal Legislation.** In April 2005, Senator Boxer introduced S 778, the Pharmacy Consumer Protection Act of 2005. S 778 would require a pharmacist to fill a legal prescription unless the prescribed item is not in the pharmacy's stock, in which case the pharmacy would order such item without unnecessary delay or, if the patient prefers, the pharmacy would transfer the prescription to a local pharmacy of the patient's choice or return the prescription to the patient, at the patient's request. S 778 would not prohibit a pharmacist from refusing to dispense a prescribed item, in accordance with standard pharmacy practice, if there is a valid medical concern that such prescribed item will cause problems due to therapeutic duplications, drug-disease contraindications, drug interactions, incorrect dosage or duration of drug treatment, drug-allergy interactions, or drug abuse or misuse. S 778 has been referred to the Senate Finance Committee.

## **8) Support & Opposition.**

Support: American Academy of Pediatrics, California District  
California Medical Association  
NARAL Pro-Choice California (if amended)  
National Association of Social Workers, California Chapter  
Planned Parenthood Affiliates of California (in concept)

Oppose: California Association for Health Services at Home (unless amended)  
California Family Alliance  
California Pharmacists Association (unless amended)  
California Retailers Association (unless amended)  
California Right to Life Committee, Inc.  
California Society of Health-System Pharmacists  
Traditional Values Coalition

## **9) History.**

2005

June 22 In committee: Set first hearing. Failed passage. Reconsideration granted.  
June 15 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.  
June 15 Referred to Coms. on HEALTH and B., P. & E.D.  
June 6 In Senate. Read first time. To Com. on RLS. for assignment.  
June 2 Read third time, passed, and to Senate. (Ayes 52. Noes 25. Page 2096.)  
May 9 Read second time. To third reading.  
May 5 From committee: Do pass. (Ayes 12. Noes 5.) (May 4).  
Apr. 27 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 2.) (April 26).  
Apr. 14 Re-referred to Com. on B. & P.  
Apr. 13 Read second time and amended.  
Apr. 12 From committee: Amend, do pass as amended, and re-refer to Com. on B. & P. (Ayes 10. Noes 3.) (April 5).

Mar. 30 Re-referred to Com. on HEALTH.  
Mar. 29 From committee chair, with author's amendments: Amend, and re-refer to Com.  
on HEALTH. Read second time and amended.  
Feb. 15 Referred to Coms. on HEALTH and B. & P.

2004

Dec. 7 From printer. May be heard in committee January 6.  
Dec. 6 Read first time. To print.

**AB 21**

**AS AMENDED: June 15, 2005**

**SENATE HEALTH**

COMMITTEE ANALYSIS  
Senator Deborah V. Ortiz, Chair

FISCAL: Business, Professions and Economic  
Development / 1  
Appropriations

CONSULTANT:  
Vazquez / ak

**SUBJECT**

Pharmacists: dispensing requirements

**SUMMARY**

This bill requires pharmacists to dispense a lawful prescription unless certain specified circumstances exist, including allowing a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug if the pharmacist satisfies certain conditions. The bill deems a violation of these provisions unprofessional conduct and harassment, as specified.

**ABSTRACT**

Existing law:

- 1.Provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy (Board) and provides that it shall be unprofessional conduct for a pharmacist to violate any provisions of law governing pharmacy.
- 2.Provides that it is unlawful, unless otherwise provided under law, for any person other than a pharmacist to dispense a prescription.
- 3.Defines "dispense" as the furnishing of drugs or devices by a pharmacist upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or upon an order to furnish drugs or transmit a prescription from a certified nurse midwife, nurse practitioner, physician assistant, or pharmacist acting within the scope of his or her practice.

4. Defines "dispense" also as the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, podiatrist, or veterinarian, or by a certified nurse midwife, nurse practitioner, or physician assistant acting within the scope of his or her practice.
5. Defines "prescription" as an oral, written, or electronic transmission that includes specified information including the name of the patient, the name and quantity of the drug or device prescribed, the condition for which being prescribed if requested, and if in writing, the signature of the prescriber issuing the order; and provides also that a prescriber's drug order that meets specified requirements may be treated as a prescription by the dispensing pharmacist.
6. Provides for the furnishing of emergency contraception (EC) drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber, or developed and approved by the Board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities.
7. Provides under general provisions of the Business and Professions Code that it shall be unprofessional conduct for a health care provider to engage in repeated acts of excessive prescribing or administering of drugs or treatment, the commission of any act of sexual abuse, misconduct, or relations with a patient, or to engage in other unprofessional conduct as specified.

This bill:

1. States that this law shall be known and may be cited as the Women's Contraceptive and Pharmaceutical Freedom Act of 2005.
2. Requires a pharmacist to dispense a lawful prescription unless one of the following circumstances exists and that violation of this section by a pharmacist constitutes unprofessional conduct subject to disciplinary action by the Board:
  - a. The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient;

- b. The pharmacy does not have the prescribed trade or brand name drug in stock, in which case requires the pharmacist to offer the patient another drug product, if available, with the same active chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as specified; or
  - c. The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to an order or prescription. Permits a pharmacist to decline to dispense a drug on these grounds only after notifying his or her employer in writing, upon acceptance of employment and immediately after any change to that decision, of the drug to which he or she objects.
3. States that it shall constitute unprofessional conduct for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress, and that for these purposes, the emotional distress shall be actual and severe as determined by a reasonable person.

#### FISCAL IMPACT

According to the Assembly Appropriations Committee, there are minor absorbable special fund costs (Pharmacy Board Contingent Fund) to the Board of Pharmacy. The Board of Pharmacy is funded by licensing fees paid by pharmacists and deposited in the Pharmacy Board Contingent Fund.

#### BACKGROUND AND DISCUSSION

##### Purpose of the bill

According to the author, current law is silent to the question of whether a pharmacist can refuse to fill a prescription for non-medical reasons. The author states that there have been a growing number of cases around the country where pharmacists have refused to dispense drugs because of personal objections. The most common cases are with hormonal contraception, but some women have been refused a drug needed for a dilatation and curettage following a miscarriage. There are incidents of pharmacist refusal around the country and most states that have looked at this issue have adopted laws to protect the pharmacist's ability to refuse. It is the author's intent that this bill provide the access to necessary medication that should be the priority of pharmacists and pharmacies in

California.

#### Reports of refusals to fill prescriptions

There have been numerous news stories throughout the United States describing incidents where pharmacists have refused to dispense oral contraceptives and other types of birth control based on moral grounds or religious beliefs. A March 28, 2005 Washington Post article reported that it is not known how often that refusals are occurring, but there have been cases in California, Washington, Georgia, Illinois, Louisiana, Massachusetts, Texas, New Hampshire, Ohio, and North Carolina. The article stated that Wisconsin is one of at least 11 states considering "conscience clause" laws that would protect pharmacists' right to decline to fill a prescription and that four states already have laws that permit pharmacists to refuse to fill prescriptions that violate their beliefs. At least four other states are considering laws that would explicitly require pharmacists to fill all prescriptions. Some large pharmacy chains, including Walgreens, Wal-Mart and CVS, have instituted policies to balance pharmacists' and customers' rights by ensuring another pharmacist is on duty to fill the prescription or contacting another pharmacy willing to fill the prescription in the case that a pharmacist objects to filling it.

#### Complaints to the Board of Pharmacy

Current law, through regulations, requires a pharmacist who declines to furnish emergency contraception (EC) based on a "conscience clause" to refer the patient to another EC provider. The law is silent on pharmacists' ability to object on religious, ethical, or moral grounds for any other drug. The Board has a system in place to receive and investigate complaints, but received none regarding refusals to fill EC prescriptions in 2004.

#### Related legislation

SB 644 (Ortiz) would require a pharmacist to dispense a lawful prescription except in specified circumstances, including on ethical, moral, or religious grounds and permits the pharmacist to decline to dispense the prescription on that basis only if his or her employer is able to reasonably accommodate that objection. SB 644 will be heard before the Assembly Committee on Business and Professions on June 21, 2005.

#### Prior legislation

SB 490 (Alpert, Chapter 651, Statutes of 2003), permits a licensed pharmacist to initiate EC drug therapy in accordance with a standardized procedure approved by the Board and the Medical Board of California. It also

requires a pharmacist, prior to furnishing EC, to complete a training program of at least one hour of approved continuing education on EC drug therapy.

#### Arguments in support

The California District of the American Academy of Pediatrics (AAP-CA) supports this bill and states that in small towns where there is only one pharmacy and pharmacist, or it is cumbersome for a woman to access alternate pharmacies, it is imperative that she be able to obtain her needed prescription or drug. AAP-CA states that a pharmacist has a right to his or her own personal belief with respect to his or her choice of personal medical treatments, however, he or she should not be able to impose those beliefs on others by restricting the availability of legal drugs. The National Association of Social Workers, California Chapter states that this measure recognizes the need to establish clear regulation and that it will ensure that clients have access to all medications they are prescribed. Planned Parenthood Affiliates of California supports the bill in concept and supports the right of every individual to have access to his or her legal prescription. NARAL Pro-Choice California additionally writes with a support if amended position and states that it is committed to working with the author on unresolved issues expressed, such as ensuring that a protocol set forth by the pharmacy allows for timely access to necessary medication for the patient and reasonable disciplinary action and enforcement.

#### Arguments in opposition

The California Association for Health Services at Home (CAHSAH) representing home health agencies and hospice providers, as well as providers of private personal care services in the home, opposes the bill and objects to the bill's lack of acknowledgement of the professional judgment of the pharmacist, and because of this absence, CAHSAH states that it will negatively impact and eliminate pharmacists' discretion when a physician is unavailable or when issues arise that impact the patients' medical condition. CAHSAH states that this could have serious adverse consequences for patients, as home health agencies provide care around the clock and operate under systems that rely on a pharmacist's professional judgment to comply with the patient care directive and plan of treatment. CAHSAH additionally raises a concern that the bill will require pharmacists to dispense medications even if they don't accept the coverage of the prescription or possibly even if the patient can't pay for it.

The California Society of Health-System Pharmacists (CSHP)

writes in opposition to subjecting a pharmacist to unprofessional conduct for acts of undefined "emotional distress" and "extreme or outrageous conduct" that places the pharmacist in an overly broad vicariously liable situation. CSHP states that the California Board of Pharmacy already has the authority to take action against any pharmacist for the reasons suggested by AB 21. For example, unprofessional conduct includes, but is not limited to, gross immorality or any act involving moral turpitude, dishonesty, fraud, deceit or corruption, citing Business and Professions Section 4301. Furthermore, CSHP objects to the mandatory dispensing approach taken by AB 21 and states that it would prefer a more passive objection for the reasons enumerated in the bill.

The Capitol Resource Institute states that this bill would compel pharmacists to violate their moral and religious convictions and openly discriminates against the religious convictions and moral dictates of a pharmacist. The California Family Alliance opposes the bill on the basis of the referral provisions as pharmacists who cannot in good conscience dispense contraceptives or morning-after pills will find it just as objectionable to refer a patron to someone who does. The California Right to Life Committee, Inc. asserts that pharmacists are professionals and must continue their right to exercise their freedom of conscience during their hours of employment.

#### Oppose unless amended

The California Pharmacists Association (CPhA) and the California Retailers Association (CRA) write with "oppose unless amended" positions on AB 21 and state that the bill as currently drafted provides for sweeping reform of pharmacy practice and will remove the professional judgment of a pharmacist from patient care, which the organizations state currently provides a check and balance on medication errors, adverse drug reaction, and unnecessary prescriptions, and furthers optimal pharmaceutical care. The CPhA and CRA request the following amendments:

Clarification of the use of professional judgment by providers.

Removal of Section 4069 from the pharmacy practice act and insertion instead into the general provisions of the Business and Professions Code.

Inclusion of a provision of standards that ensure access to prescription products without imposing unrealistic burdens on providers.



Establishment of a respectful right of conscience clause for providers that also ensures that patients receive access to medications.

Clarification of coverage and payment issues that create unintended consequences.

Imposition of a penalty of unprofessional conduct for violation of its provisions.

#### Author's amendments

The author has offered the following two amendments to address some of the concerns raised by the opposition:

1. The intent of the following amendment is to address the concern raised around a pharmacist's ability to access a prescriber who may not be directly available:

On page 2, line 13, after "prescriber" insert "or any other treating or supervising physician who is authorized by the patient's prescriber to treat the patient"

2. The intent of the following amendment is to address concerns raised around a "mandate to dispense" and how this might affect payment arrangements and requirements:

On page 3, line 15, insert a new subdivision (d) to read: "This section imposes no duty on a pharmacist to dispense a lawful prescription without payment for the prescription, including payment directly by the patient or through a third party payer accepted by the licensee or payment or any required copayment by the patient."

#### Additional questions for the Committee

1. Accuracy of title. The title on page 2, lines 1-2 currently calls this law the "Women's Contraceptive and Pharmaceutical Freedom Act of 2005." Given that the bill affects all drugs and not only contraception, should the title be revised to reflect this?
2. Duplication of generic substitution section. The bill currently provides for generic substitution if a drug is not in stock and restates the authority that exists in current law, Section 4073 of the Business and Professions Code. Does the author wish to consider removal of this duplicative language?

3. Pharmacists currently employed. The bill specifies that a pharmacist shall provide notification upon acceptance of employment and immediately after any change to that decision. It is implied that current pharmacist employees shall notify their employer if they decide that they will decline to dispense. Arguably, the bill needs clarification because it requires notification to be given upon acceptance of employment by new employees and it is unclear when current employees would need to provide this. What is the procedure for current employees and can this be reconciled to the requirement for the newly employed?
4. Employer requirement. The bill currently states that a violation by a pharmacist constitutes unprofessional conduct, but does not provide for consequences for an employer who does not accommodate a pharmacist's objections and a patient's need for the drug. Can a standard for employer accommodation be included in the bill to enable enforcement for this section of the bill?
5. Meaning and enforcement of harassment provisions. The bill states that it shall constitute unprofessional conduct for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress, and that for these purposes, the emotional distress shall be actual and severe as determined by a reasonable person. What are the definitions of various terms used in this section, including "extreme or outrageous conduct" and "reckless indifference"? Is this enforceable and is the current complaint system adequate to ensure that this anti-harassment policy is meaningful?
6. Technical amendment . On page 2, line 24, the author may wish to consider adding after the word "drug" the language "or class of drugs" to allow for the notification and conscience clause to apply to more than individual drugs to facilitate the effectiveness of the bill.

#### PRIOR ACTIONS

Assembly Floor: 52 - 25 Pass  
Assembly Appropriations: 12 - 5 Do Pass  
Assembly B & P: 7 - 2 Do Pass

Assembly Health: 10 - 3 Do Pass as Amended

#### POSITIONS

Support: American Academy of Pediatrics, California District  
California Medical Association  
NARAL Pro-Choice California (if amended)  
National Association of Social Workers,  
California Chapter  
Planned Parenthood Affiliates of California (in  
concept)

Oppose: California Association for Health Services at Home  
(unless amended)

California Family Alliance  
California Pharmacists Association (unless  
amended)  
California Retailers Association (unless amended)  
California Right to Life Committee, Inc.  
California Society of Health-System Pharmacists  
Capitol Resource Institute  
Traditional Values Coalition

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AMENDED IN ASSEMBLY JULY 5, 2005

AMENDED IN SENATE MAY 18, 2005

AMENDED IN SENATE MAY 4, 2005

AMENDED IN SENATE APRIL 7, 2005

**SENATE BILL**

**No. 644**

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**Introduced by Senator Ortiz**

*(Principal coauthor: Assembly Member Levine)*

**(Coauthors: Senators ~~Kuehl~~ Alquist, Figueroa, Kuehl, and Romero)**

*(Coauthors: Assembly Members ~~Frommer~~, Jones, Berg, Cohn, Frommer, Goldberg, Jones, Koretz, and Laird)*

February 22, 2005

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An act to add Section 733 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 644, as amended, Ortiz. Dispensing prescription drugs and devices.

Existing law makes certain actions by a health care professional unprofessional conduct subject to disciplinary action by the licensing board regulating the health care professional.

This bill would include within those provisions, a requirement that a health care licentiate dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. The bill would authorize the licentiate to decline to dispense the prescription or order on that basis only if the licentiate notified his or her employer of the objection and it can be reasonably accommodated. The bill would

require the licentiate's employer in those circumstances to establish protocols to ensure a patient's timely access to the prescribed drug or device.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. It is the intent of the Legislature that health care  
2 professionals dispense prescription drugs and devices in a timely  
3 way or provide appropriate referrals for patients to obtain the  
4 necessary prescription drugs and devices, despite the health care  
5 professional's objection to dispensing the drugs or devices on  
6 ethical, moral, or religious grounds.

7 SEC. 2 Section 733 is added to the Business and Professions  
8 Code, to read:

9 733. (a) No licentiate shall obstruct a patient in obtaining a  
10 prescription drug or device that has been legally prescribed or  
11 ordered for that patient. A violation of this section constitutes  
12 unprofessional conduct by the licentiate and shall subject the  
13 licentiate to disciplinary action by his or her licensing agency.

14 (b) Notwithstanding any other provision of law, a licentiate  
15 shall dispense drugs and devices, as described in subdivision (a)  
16 of Section 4024, pursuant to a lawful order or prescription unless  
17 one of the following circumstances exists:

18 (1) Based solely on the licentiate's professional training and  
19 judgment, dispensing pursuant to the order or the prescription is  
20 contrary to law, or the licentiate determines that the prescribed  
21 drug or device would cause a harmful drug interaction or would  
22 otherwise adversely affect the patient's medical condition.

23 (2) The prescription drug or device is not in stock. If an order,  
24 *other than an order described in Section 4019*, or prescription  
25 cannot be dispensed because the drug or device is not in stock,  
26 the licentiate shall take one of the following actions:

27 (A) Immediately notify the patient and arrange for the drug or  
28 device to be delivered to the site or directly to the patient in a  
29 timely manner.

30 (B) Promptly transfer the prescription to another pharmacy  
31 known to stock the prescription drug or device that is near  
32 enough to the site from which the prescription or order is

1 transferred, to ensure the patient has timely access to the drug or  
2 device.

3 (C) Return the prescription to the patient and refer the patient  
4 . The licentiate shall make a reasonable effort to refer the patient  
5 to a pharmacy that stocks the prescription drug or device that is  
6 near enough to the referring site to ensure that the patient has  
7 timely access to the drug or device.

8 (3) The licentiate refuses on ethical, moral, or religious  
9 grounds to dispense a drug or device pursuant to an order or  
10 prescription. A licentiate may decline to dispense a prescription  
11 drug or device on this basis only if the licentiate has previously  
12 notified his or her employer, in writing, of the drug or class of  
13 drugs to which he or she objects, and the licentiate's employer  
14 can, without creating undue hardship, provide a reasonable  
15 accommodation of the licentiate's objection. The licentiate's  
16 employer shall establish protocols that ensure that the patient has  
17 timely access to the prescribed drug or device despite the  
18 licentiate's refusal to dispense the prescription or order. For  
19 purposes of this section, "reasonable accommodation" and  
20 "undue hardship" shall have the same meaning as applied to  
21 those terms pursuant to subdivision-(e)(l) of Section 12940 of the  
22 Government Code.

23 (c) For the purposes of this section, "prescription drug or  
24 device" has the same meaning as the definition in Section 4022.

25 (d) The provisions of this section shall apply to the drug  
26 therapy described in paragraph (8) of subdivision (a) of Section  
27 4052.

28 (e) This section imposes no duty on a licentiate to dispense a  
29 drug or device pursuant to a prescription or order without  
30 payment for the drug or device, including payment directly by  
31 the patient or through a third party payer accepted by the  
32 licentiate or payment of any required copayment by the patient.  
33

34  
35 CORRECTIONS: \_\_\_\_\_

36 Heading-Page 1.  
37 \_\_\_\_\_

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# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: SB 644**

**VERSION: AMENDED JULY 5, 2005**

**AUTHOR: ORTIZ**

**SPONSOR: PLANNED PARENTHOOD**

**RECOMMENDED POSITION:**

**SUBJECT: DISPENSING PRESCRIPTION DRUG AND DEVICES**

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### **Existing Law:**

- 1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052 (8))
- 2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)
- 3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)

### **This Bill:**

- 1) States that no licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary action by his or her licensing agency.
- 2) Requires a licentiate to dispense drugs and devices pursuant to a lawful order or prescription unless one of the following circumstances exists:
  - a. Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.
  - b. The prescription drug or device is not in stock. If an order or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:
    - i. Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.
    - ii. Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device and that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

- iii. Return the prescription to the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.
  - c. The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription, if:
    - i. The licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects; and
    - ii. The licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection by establishing protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order.
- 3) States that the section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third party payer accepted by the licentiate or payment of any required copayment by the patient.
- 4) Defines "reasonable accommodation" and "undue hardship" in accordance with the Government Code.

(B&P 733 Added)

**Comment:**

**1) Author's Intent.** The sponsor intent is to establish in law a duty to fill lawful prescriptions while balancing a licensee's right to ethical, moral or religious objections with a patient's right to basic health care.

**2) In the News.** The issue on whether or not a pharmacist has a right to refuse to fill a prescription has been debated in the news and in state legislatures over the last year. The Washington Post reports that twelve states either have laws or are considering laws that would allow a pharmacist not to fill a prescription. While much of the debate has centered on birth control and EC, there are increasing news reports and web postings that indicate this issue is likely to expand into other moral issues such as assisted suicide, sterile needle programs, and pain management.

**3) Unprofessional Conduct.** SB 644 has an unprofessional conduct provision in the measure. The inclusion of this provision would remove the board's executive officer's discretion to cite and fine a pharmacist that refuse to dispense a prescription in accordance with the law, and would require that the enforcement case be referred to the attorney generals (AG) office. Under current law the executive officer has the option of using administrative cite and fine penalties or referring a case to the AG's office. If SB 644 is enacted all cases involving a pharmacist refusal to dispense a prescription will be referred directly to the AG's office.

**4) Enforcement.** Enforcement of SB 644 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacist's refusal to dispense EC. Consequently, if SB 644 were enacted, the board does not anticipate a huge increase in consumer complaints regarding refusal to fill prescriptions.

**5) Legislative History.** Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

**6) Related Legislation.** AB 21 (Levine 2005) Pharmacists: Practice Requirements, would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she has notified his or her employer in writing. The bill would make a violation of its provisions unprofessional conduct, subject to disciplinary action by the board. AB 21 failed passage when it was heard in the Senate Committee on Health on June 22, 2005 by a vote of 4-4 and was granted reconsideration.

**7) Federal Legislation.** In April 2005, Senator Boxer introduced S 778, the Pharmacy Consumer Protection Act of 2005. S 778 would require a pharmacist to fill a legal prescription unless the prescribed item is not in the pharmacy's stock, in which case the pharmacy would order such item without unnecessary delay or, if the patient prefers, the pharmacy would transfer the prescription to a local pharmacy of the patient's choice or return the prescription to the patient, at the patient's request. S 778 would not prohibit a pharmacist from refusing to dispense a prescribed item, in accordance with standard pharmacy practice, if there is a valid medical concern that such prescribed item will cause problems due to therapeutic duplications, drug-disease contraindications, drug interactions, incorrect dosage or duration of drug treatment, drug-allergy interactions, or drug abuse or misuse. S 778 has been referred to the Senate Finance Committee.

**8) Substantive Amendments since the April 27<sup>th</sup> Board Meeting.** The addition of the provision that violating the provisions of the chapter would constitute unprofessional conduct.

**9) Support / Opposition.**

Support: Planned Parenthood Affiliates of California (sponsor)  
NARAL Pro-Choice California (sponsor)  
American Association of University Women (sponsor)  
California Family Health Council (sponsor)  
American Civil Liberties Union  
American College of Obstetricians and Gynecologists  
California Academy of Family Physicians  
California Association for Nurse Practitioners  
California Commission on the Status of Women  
California Medical Association  
California National Organization for Women  
California Nurses Association  
California Nurse Midwife Association  
California Pharmacists Association  
California State Board of Pharmacy  
City of West Hollywood  
National Association of Social Workers  
National Organization for Women, Oakland East Bay Chapter

Opposition: California Catholic Conference  
California Family Alliance  
California Nurses for Ethical Standards  
California ProLife Council, Inc  
Capitol Resource Institute

**10) History.**

2005  
June 21 From committee: Do pass, but first be re-referred to Com. On HEALTH. (Ayes 8.  
Noes 2.) Re-referred to Com. on HEALTH  
June 9 To Coms. on B. & P. and HEALTH

May 26 In Assembly. Read first time. Held at Desk.  
 May 26 Read third time. Passed. (Ayes 26. Noes 13. Page 1190.) To Assembly.  
 May 25 Read second time. To third reading.  
 May 24 From committee: Do pass. (Ayes 8. Noes 5. Page 1147.)  
 May 18 From committee with author's amendments. Read second time. Amended. Re-referred to committee.  
 May 16 Set for hearing May 23.  
 May 4 Read second time. Amended. Re-referred to Com. on APPR.  
 May 3 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 3. Page 847.)  
 Apr. 26 From committee: Do pass, but first be re-referred to Com. On HEALTH. (Ayes 4. Noes 3. Page 770.) Re-referred to Com. On HEALTH  
 Apr. 13 Set for hearing April 25.  
 Apr. 12 Reset for hearing April 27 in HEALTH pending receipt.  
 Apr. 11 Set for hearing April 20 in HEALTH pending receipt.  
 Apr. 7 From committee with author's amendments. Read second time. Amended. Re-referred to committee.  
 Mar. 17 Set for hearing April 11.  
 Mar. 3 To Coms. on B., P. & E.D. and HEALTH  
 Feb. 24 From print. May be acted upon on or after March 26.  
 Feb. 22 Introduced. Read first time. To Com. on RLS. for assignment. To print.

**SB 644**

**As Amended: May 18, 2005**

**ASSEMBLY COMMITTEE ON HEALTH**

Wilma Chan, Chair

SENATE VOTE : 26-13

SUBJECT : Dispensing prescription drugs and devices.

SUMMARY : Requires a licentiate of the Board of Pharmacy (Board), as specified, to dispense drugs and devices pursuant to a lawful order or prescription unless specified circumstances exist. Specifically, this bill :

- 1) States that it is the intent of the Legislature that health care professionals dispense prescription drugs and devices in a timely way or provide appropriate referrals for patients to obtain the necessary prescription drugs and devices, despite the health care professional's objection to dispensing the drugs or devices on ethical, moral, or religious grounds.
- 2) Requires a licentiate Board, as specified, to dispense drugs and devices pursuant to a lawful order or prescription unless, based solely on the professional training and judgment of the licentiate, it would be contrary to law or the licentiate determines that the drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.
- 3) Prohibits a licentiate from obstructing a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. Specifies that a violation of this bill constitutes unprofessional conduct by the licentiate and subjects the licentiate to disciplinary action by the Board of Pharmacy.
- 4) Provides that a licentiate does not have to dispense a prescription drug or device as defined if it is not in stock, but requires the licentiate to:
  - a) Immediately notify the patient and arrange for the drug or device to be delivered to the pharmacy or to the patient in a timely manner;
  - b) Promptly transfer the prescription to another pharmacy known to stock the drug or device and that is near enough to ensure that the patient has timely access; or,

- c) Return the prescription to the patient and refer the patient to a pharmacy for which the licentiate has made a reasonable effort to ascertain that the drug or device is in stock and that is near enough to the referring pharmacy to ensure timely access.
- 5) Requires a licentiate, if he or she refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription, to inform his or her employer in advance and in writing of the drug or class of drugs to which he or she objects.
- 6) Permits the licentiate's employer to provide reasonable accommodation, as defined, to the licentiate's refusal to dispense by establishing protocols that ensure that the patient has timely access to the prescribed drug or device as long as such protocols would not create an undue hardship.
- 7) Defines the terms "reasonable accommodation" and "undue hardship" as having the same meaning as those relating to unlawful employment practices and requirements of employers to provide reasonable accommodation of an employee's religious beliefs and observances, as long as they do not create undue hardship on the conduct or operation of its business.
- 8) Defines "prescription drug or device" as those drugs or devices defined as a "dangerous drug" or "dangerous device" and those drugs identified as those for purposes of EC drug therapy.
- 9) Applies the provisions of this bill to over-the-counter EC drug therapy as defined in current law.
- 10) Imposes no duty on a licentiate to dispense a prescription drug or device without payment for the drug or device, including payment directly by the patient, through a third party payer, or payment of any required copayment by the patient.

EXISTING LAW provides for the licensure and regulation of pharmacists by the Board and prohibits, except as specified, a person other than a pharmacist from dispensing a dangerous drug, as defined, pursuant to a prescription.

FISCAL EFFECT : According to the Senate Appropriations Committee analysis, costs of \$100,000 in special funds per year for enforcement. The Pharmacy Board identifies a possible minor fiscal impact to the Board if it opts to pursue disciplinary action against pharmacists who refuse to fill a prescription without following the protocols provided by this bill.

## COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, pharmacists provide an essential service to consumers who rely on their expertise to access medically necessary prescription medications and supplies. There is, however, no legal duty on a pharmacist to dispense medications and other prescription items to an individual with a lawful prescription. Existing law simply authorizes persons with particular training and competency to dispense prescription drugs. As a consequence, a pharmacist can legally refuse to fill a legal prescription at his or her discretion. There have been a number of reports in the past year or so that retail pharmacists are refusing to fill lawful prescriptions, particularly prescriptions for contraception, including Emergency Contraception (EC), based on individual pharmacists religious beliefs. While there is no intent in this bill to override the religious beliefs of individuals, the purpose of the bill is to ensure that consumers are not abandoned by pharmacists and pharmacies, and will have timely access to necessary medications even where an individual pharmacist will not dispense the drug requested.

2)REPORTS OF REFUSALS TO FILL PRESCRIPTIONS . There have been numerous news stories throughout the United States describing incidents where pharmacists have refused to dispense oral contraceptives and other types of birth control based on moral grounds or religious beliefs. A March 28, 2005 Washington Post article reported that it is not known how often that refusals are occurring, but there have been cases in California, Washington, Georgia, Illinois, Louisiana, Massachusetts, Texas, New Hampshire, Ohio, and North Carolina. The article stated that Wisconsin is one of at least 11 states considering "conscience clause" laws that would protect pharmacists' right to decline to fill a prescription and that four states already have laws that permit pharmacists to refuse to fill prescriptions that violate their beliefs. At least four other states are considering laws that would explicitly require pharmacists to fill all prescriptions. Some large pharmacy chains, including Walgreens, Wal-Mart and CVS, have instituted policies to balance pharmacists' and customers' rights by ensuring another pharmacist is on duty to fill the prescription or contacting another pharmacy willing to fill the prescription in the case that a pharmacist objects to filling it.

3)COMPLAINTS TO THE BOARD OF PHARMACY . Current law, through regulations, requires a pharmacist who declines to furnish EC based on a "conscience clause" to refer the patient to another EC provider. The law is silent on pharmacists' ability to object on religious, ethical, or moral grounds for any other drug. The Board has a system in place to receive and

investigate complaints, but received none regarding refusals to fill EC prescriptions in 2004.

4)RELATED LEGISLATION . AB 21 (Levine) is similar to this bill and would require a pharmacist to dispense a prescription except in specified circumstances, and permit a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. AB 21 failed passage when it was heard in the Senate Committee on Health on June 22, 2005 by a vote of 4-4 and was granted reconsideration.

5)PREVIOUS LEGISLATION . SB 490 (Alpert), Chapter 651, Statutes of 2003, permits a licensed pharmacist to initiate EC drug therapy in accordance with a standardized procedure approved by the Board and the Medical Board of California. It also requires a pharmacist, prior to furnishing EC, to complete a training program of at least one hour of approved continuing education on EC drug therapy.

6)SUPPORT . NARAL Pro-Choice California, the California Association for Nurse Practitioners, and the California Nurse Midwives Association write this bill will make sure that all individuals have access to their prescription medication in a timely manner, while respecting the rights of pharmacists. The American Association of University Women (AAUW) write that they support the right of an individual to object on ethical, moral or religious grounds to performing an act that is in conflict with the person's beliefs. However, AAUW also believes that pharmacies have a responsibility to ensure that patients receive needed medications in a timely and respectful manner. The American Civil Liberties Union supports the careful balance struck by this bill that would protect the rights of patients and health care licentiates. The American College of Obstetricians and Gynecologists believe that this bill respects a pharmacist's right to exercise their conscience while ensuring patients have timely access to essential, prescribed medications. The California Pharmacists Association states that it is appropriate to codify a practice of "dispense or refer" that is correct and enforceable, which this bill accomplishes.

7)OPPOSITION . The California Family Alliance states that this bill does not contain the necessary safeguard to protect pharmacists with sincerely held religious beliefs and that under the accommodation requirement of this bill, a pharmacist employer does not need to allow the pharmacist the right of conscience where there is an "undue hardship" on the employer. The California Catholic Conference contends that conscience objections would have to yield to the need to dispense the drugs due to an "undue hardship" on the employer or other



entity, which would thereby render the conscience clause inoperative upon someone's complaint. California ProLife Council writes that this bill does not make it clear whether or not a pharmacist would be able to refuse the dispensing of abortive drugs. The Capitol Resource Institute states that if this bill were to pass, California would be the first state to compel pharmacists to violate their moral and religious convictions and distribute contraceptives and abortifacients. California Nurses for Ethical Standards writes that this bill makes it more difficult for pharmacists to abide their consciences.

#### REGISTERED SUPPORT / OPPOSITION :

##### Support

Planned Parenthood Affiliates of California (sponsor)  
NARAL Pro-Choice California (sponsor)  
American Association of University Women (sponsor)  
California Family Health Council (sponsor)  
American Civil Liberties Union  
American College of Obstetricians and Gynecologists  
California Academy of Family Physicians  
California Association for Nurse Practitioners  
California Commission on the Status of Women  
California Medical Association  
California National Organization for Women  
California Nurses Association  
California Nurse Midwife Association  
California Pharmacists Association  
California State Board of Pharmacy  
City of West Hollywood  
National Association of Social Workers  
National Organization for Women, Oakland East Bay Chapter

##### Opposition

California Catholic Conference  
California Family Alliance  
California Nurses for Ethical Standards  
California ProLife Council, Inc  
Capitol Resource Institute

Analysis Prepared by : Melanie Moreno / HEALTH / (916)  
319-2097

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# **Attachment 6**

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AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY MAY 9, 2005

AMENDED IN ASSEMBLY MAY 2, 2005

AMENDED IN ASSEMBLY APRIL 13, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

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**ASSEMBLY BILL****No. 283**

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**Introduced by Assembly Member Koretz**  
**(Coauthor: Assembly Member Maze)**  
(Coauthors: Senators Alquist and Margett)

February 9, 2005

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An act to add Section 11100.01 to the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 283, as amended, Koretz. Ephedrine and pseudoephedrine: retail sale.

(1) Under existing law, a retailer who makes an over-the-counter retail sale of ephedrine or pseudoephedrine is generally subject to a 3 package per transaction limitation or 9 gram per transaction limitation. Any violation of this requirement is a crime, punishable as specified.

This bill would provide that the dispensing, sale, or distribution at retail of any compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine shall be subject to specified additional requirements. The retailer would be required to store and display the product in a locked cabinet or as specified and the transaction would be required to be made by a retailer or employee of a retailer who meets specified requirements. A violation of any of

these provisions would be a misdemeanor, punishable as specified, except that (1) a retail clerk who fails to comply with these provisions would not be subject to any civil, criminal, or other penalty, unless the clerk is a willful participant in an ongoing criminal conspiracy to violate these provisions; and (2) a retailer whose employee sells pseudoephedrine or ephedrine in violation of these provisions would not be ~~liable~~ *guilty of a crime or subject to a civil penalty under the bill's provisions*, if the retailer complies with the storage and display requirements and can document that an employee training program was conducted to train employees on compliance with these provisions. *The bill would provide, however, that its provisions shall not alter or affect any cause of action or remedy otherwise available to a consumer under the law.* By creating new crimes, this bill would impose a state-mandated local program upon local governments.

(2) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 11100.01 is added to the Health and  
2 Safety Code, to read:  
3 11100.01. (a) In addition to any requirement specified in  
4 Section 11100, the dispensing, sale, or distribution at retail of any  
5 compound, mixture, preparation, or product that contains any  
6 detectable quantity of ephedrine, pseudoephedrine, or any  
7 derivative of ephedrine or pseudoephedrine, or any detectable  
8 quantity of any salt, optical isomer, or salt of an optical isomer of  
9 ephedrine, pseudoephedrine, or any derivative of ephedrine or  
10 pseudoephedrine, shall be subject to the following requirements:  
11 (1) Any product specified in subdivision (a) shall be stored or  
12 displayed by a retailer in a locked cabinet or in such a manner  
13 that the product is accessible to the public only with the  
14 assistance of the retailer or employee of the retailer. The retailer

1 or employee of the retailer shall at all times act to prevent the  
2 theft or diversion of the product.

3 (2) The dispensing, sale, or distribution at retail of any  
4 product specified in subdivision (a) shall be made only by a  
5 retailer or employee of a retailer who is trained in the legal  
6 requirements set forth in this section and who shall at all times  
7 act to prevent the theft or diversion of the product.

8 (b) This section shall not apply to any product specified in  
9 subdivision (a) in liquid, liquid capsule, or dissolvable strip form  
10 in which ephedrine, pseudoephedrine, or any derivative of  
11 ephedrine or pseudoephedrine is the active ingredient.

12 (c) (1) The Department of Justice may adopt rules and  
13 regulations in accordance with Chapter 3.5 (commencing with  
14 Section 11340) of Part 1 of Division 3 of Title 2 of the  
15 Government Code that exempt a substance from the application  
16 of subdivision (a) if the department finds that the substance is not  
17 used in the unlawful manufacture of methamphetamine or any  
18 other controlled substance.

19 (2) The Department of Justice shall, upon satisfactory  
20 application by the manufacturer of a drug product to the  
21 department, exempt any product the department determines to  
22 have been formulated in such a way as to effectively prevent the  
23 conversion of any active ingredient in the product into  
24 methamphetamine or any other controlled substance.

25 (d) Except as provided in subdivision (e), any person who  
26 violates this section shall be punished as follows:

27 (1) A first violation of this section is a misdemeanor.

28 (2) Any person who has previously been convicted of a  
29 violation of this section or Section 11100 shall, upon a  
30 subsequent conviction thereof, be punished by imprisonment in a  
31 county jail not exceeding one year, by a fine not exceeding ten  
32 thousand dollars (\$10,000), or by both the fine and  
33 imprisonment.

34 (e) Notwithstanding subdivision (d), liability for a violation of  
35 this section shall not be imposed in the following cases:

36 (1) A retail clerk who fails to comply with the provisions of  
37 subdivision (a) shall not be guilty of a crime pursuant to  
38 subdivision (d), shall not be subject to any civil penalty, and shall  
39 not be subject to any disciplinary action

1 or discharge by his or her employer, except if the retail clerk is  
2 a willful participant in an ongoing criminal conspiracy to violate  
3 this section.

4 (2) A retailer whose employee sells pseudoephedrine or  
5 ephedrine in violation of this section shall not be ~~liable~~ *guilty of*  
6 *a crime pursuant to subdivision (d) and shall not be subject to*  
7 *any civil penalty under this subdivision*, if the retailer complies  
8 with paragraph (1) of subdivision (a) and can document that an  
9 employee training program was conducted to train employees on  
10 compliance with this section.

11 (3) *Nothing in this subdivision shall alter or affect any cause*  
12 *of action or remedy otherwise available to a consumer under the*  
13 *law.*

14 (f) It is the intent of the Legislature that this section and  
15 Section 11100 shall preempt all local ordinances or regulations  
16 governing the sale by a retail distributor of over-the-counter  
17 products containing pseudoephedrine.

18 SEC. 2. No reimbursement is required by this act pursuant to  
19 Section 6 of Article XIII B of the California Constitution because  
20 the only costs that may be incurred by a local agency or school  
21 district will be incurred because this act creates a new crime or  
22 infraction, eliminates a crime or infraction, or changes the  
23 penalty for a crime or infraction, within the meaning of Section  
24 17556 of the Government Code, or changes the definition of a  
25 crime within the meaning of Section 6 of Article XIII B of the  
26 California Constitution.





# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 283**

**VERSION: MAY 26, 2005**

**AUTHOR: KORETZ**

**SPONSOR: KORETZ**

**RECOMMENDED POSITION: NO POSITION**

**SUBJECT: EPHEDRINE AND PSEUDOEPHEDRINE: RETAIL SALE**

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### **Existing Law:**

- 1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))
- 2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))
- 3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

### **This Bill:**

- 1) Requires that the dispensing, sale, or distribution at retail of any compound, mixture, preparation, or product that contains any detectable quantity of ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine, of or any detectable quantity of any salt, optical isomer, or salt of an optical isomer of ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine, shall be subject to the following requirements:
  - a. The products be stored or displayed by a retailer in a locked cabinet or locked area in such a manner that the product is accessible to the public only with the assistance of the retailer or employee of the retailer. The retailer or the employee of a retailer shall act to prevent the theft or diversion of the products.
  - b. The sale of products shall be made only by a retailer or employee of a retailer who is trained in the legal requirements set forth in this section and who shall at all times act to prevent the theft or diversion of the products.
- 2) Sets the following penalties for any person who violate the measure:
  - a. A first violation of the measure would be a misdemeanor.
  - b. Subsequent violations and convictions would be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars (\$10,000), or by both the fine and imprisonment.

- 3) Specifies that a retail clerk who fails to comply with this law will not be guilty of a crime, or subject to civil penalties, or disciplinary action or discharge by his or her employer, except if the retail clerk is a willful participant in an ongoing criminal conspiracy to violate this section.
- 4) Specifies that a retailer whose employee sells pseudoephedrine or ephedrine in violation of this section shall not be guilty of a crime if the retailer has complied with the provision of the measure.
- 5) Allows the Department of Justice (DOJ) to adopt rules and regulations that exempt a drug product if the department finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.
- 6) This measure would not apply to any product in liquid, liquid capsule, or dissolvable strip form in which ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine is not the only active ingredient.

(H&S 11100.01 Added)

### **Comment:**

**1) Author's Intent.** The author's intent is to reduce the proliferation of methamphetamine (meth) user labs by limiting the availability of ephedrine and pseudoephedrine; an ingredient used in making meth. (A user lab is a small-scale meth production lab that supplies one to a few meth users.)

The author's district includes the City of West Hollywood, where meth has become the party drug of choice the in the gay male community. Author's staff states that a person taking meth is three times as more likely then someone not taking the drug to test positive for HIV.

**2) DOJ Tracks Distribution of Ephedrine and Pseudoephedrine Products.** The DOJ permits wholesale distributors of all precursor chemicals for meth production, including ephedrine and pseudoephedrine. Under the conditions of a permit a wholesaler must report to the DOJ, all sales and transactions of product, including sales to drug stores. The DOJ reviews the data it receives from these reports, and if anomalies are found, such as a spike in quantity sold, the DOJ will initiate an investigation to determine the cause and source of the anomaly.

**3) Retail Chains' Voluntary Efforts.** In an effort to combat illegal methamphetamine production, the following major drug retailers have voluntarily agreed to move all single ingredient pseudoephedrine products behind the pharmacy counter: Albertsons, CVS, Longs Drugs, Kmart, Rite Aid, Shopko, Target, Walgreens, and Wal-mart. Additionally, the National Association of Chain Drug Stores, which represents more than 36,000 pharmacies, supports federal legislation (S 103) to reduce access to pseudoephedrine products, including requiring the sale of pseudoephedrine products behind the pharmacy counter by a licensed pharmacist or pharmacy personnel.

**4) Based on Oklahoma Law.** AB 283 is based on Oklahoma HB 2176 (2004) which went into effect in April 2004. Law enforcement in Oklahoma hope that other states will enact similar provisions.

**5) State Legislation.** SB 152 (Speier 2005) Pseudoephedrine is similar to AB 283 in its attempt to restrict the sale of pseudoephedrine for illegal uses. SB 152 would require 1) the product be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. SB 152 would place these provisions in B&P 4051.1. SB 152 is in the Senate B&P Committee and is a two-year bill.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

**6) Federal Legislation.** In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures have been referred to their respective Committees on the Judiciary for hearing.

## **7) Support & Opposition.**

Support: American Federation of State, County, and Municipal Employees (AFSCME)  
Being Alive South Bay  
California Grocers Association  
California Retailers Association  
California State Sheriff's Association  
California STD Controllers Association  
Gay and Lesbian Social Services  
Gray Panthers  
Honorable Henry Waxman, U.S. Representative, 30th District, California  
Internet Sexuality Information Services, Inc.  
Los Angeles County Sheriff's Department  
Pharmacists Planning Service, Inc.  
Rite Aid  
San Bernardino County, Office of the Sheriff  
San Francisco AIDS Foundation  
San Francisco City and County  
Solano County Board of Supervisors  
Stop AIDS Project  
Transgender Law Center

Opposition: Pfizer Inc (Oppose unless amended)  
Schering-Plough (Oppose unless amended)

## **8) History.**

2005

July 11 In committee: Set, second hearing. Hearing canceled at the request of author.  
June 27 In committee: Set first hearing. Failed passage. Reconsideration granted.  
June 9 Referred to Coms. on B., P. & E.D. and PUB. S.  
June 1 In Senate. Read first time. To Com. on RLS. for assignment.  
May 31 Read third time, passed, and to Senate. (Ayes 72. Noes 6. Page 1851.)  
May 26 Read third time, amended, and returned to third reading.  
May 23 Read second time. To third reading.  
May 19 From committee: Do pass. (Ayes 15. Noes 3.) (May 18).  
May 11 In committee: Hearing postponed by committee.  
May 10 Re-referred to Com. on APPR.  
May 9 From committee chair, with author's amendments: Amend, and re-refer to Com. on APPR. Read second time and amended.  
May 3 Re-referred to Com. on APPR.  
May 2 Read second time and amended.  
Apr. 28 From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 5. Noes 0.) (April 26).  
Apr. 19 In committee: Hearing postponed by committee.

Apr. 14	Re-referred to Com. on PUB. S.
Apr. 13	From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
Mar. 14	Referred to Com. on PUB. S.
Feb. 10	From printer. May be heard in committee March 12.
Feb. 9	Read first time. To print.

**AB 283**

**As Amended: May 26, 2005**

**SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC  
DEVELOPMENT**

Senator Liz Figueroa, Chair

Bill No:      Author:Koretz  
Fiscal: Yes

SUBJECT: Ephedrine and pseudoephedrine: retail sale.

SUMMARY: Requires a retailer to store any compound, mixture, preparation, or product that contains any detectable quantity of ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine, or any detectable quantity of salt, optical isomer, or salt of an optical isomer of ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine in a locked cabinet, or in such a manner that the product is accessible only with the assistance of the retailer or an employee of the retailer. This bill is similar to SB 152 (Speier), as it was proposed to be amended in this Committee, which was defeated.

Existing law: Uniform Controlled Substances Act:

- 1)Defines "retail distributor" as a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of pseudoephedrine products, are limited exclusively to the sale of pseudoephedrine products for personal use both in the number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.
- 2)Requires retailer distributors and pharmacists that sell, transfer, or otherwise furnish pseudoephedrine to any person or entity in this state to submit a report of all those transactions to the Department of Justice (DOJ), as specified.
- 3)Exempts retailer distributors and pharmacists from reporting to DOJ, if pseudoephedrine is lawfully sold, transferred, or furnished over-the-counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act, and as long as the individual transaction does not involve more than three packages or nine grams of pseudoephedrine.

- 4) Makes it a misdemeanor for any retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain pseudoephedrine, or knowingly sell more than nine grams of pseudoephedrine, other than pediatric liquids as defined, and provides that a retail distributor may be imprisoned for no more than one year or be fined up to ten thousand dollars (\$10,000) for a subsequent violation.
- 5) Defines "pediatric liquids" as a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure and provides that in no instance should the dosage units exceed 15 milligrams of pseudoephedrine per 5 millimeters of liquid product, unless for children under 2 years of age when the dosage unit should not exceed 2 milliliters nor one fluid ounce for total package content.
- 6) Makes it a felony for any person who, with intent to manufacture methamphetamine, possesses pseudoephedrine.
- 7) Requires the DOJ to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances, and for those practitioners to provide information to DOJ, as specified.
- 8) Requires CURES to operate under existing provisions of law to safeguard the privacy and confidentiality of patients and requires that data obtained from CURES only be provided to appropriate state, local and federal persons as specified and not to be disclosed, sold, or transferred to any third party.
- 9) Provides that DOJ may release to a licensed health care practitioner or a pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, but that the information released shall be considered as medical information subject to provisions of the state's Confidentiality of Medical Information Act.

Existing law, the Stop Tobacco Access to Kids Enforcement Act:

- 1) Prohibits a retailer of tobacco products from selling, offering for sale, or displaying for sale, any tobacco product or tobacco paraphernalia by self-service display.

- 2) Defines "self-service display" as an open display of tobacco products or tobacco paraphernalia in a manner that is accessible to the general public without the assistance of the retailer or employee of the retailer.
- 3) Subjects a retailer to civil penalties as specified for selling tobacco products or paraphernalia by self-service display.

This bill:

- 1) Requires a retailer to store or display products containing any detectable amount of ephedrine or pseudoephedrine, or any derivative of ephedrine or pseudoephedrine, or any detectable quantity of salt, optical isomer, or salt of an optical isomer of ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine in a locked cabinet or in such a manner that the product is accessible to the public only with the assistance of the retailer or an employee of the retailer.
- 2) Requires the retailer and employees of the retailer to at all times act to prevent the theft or diversion of any of the above listed products.
- 3) Requires any retailer or employee of a retailer who dispenses, sells, or distributes any of these products to be trained in the legal requirements set forth in this bill.
- 4) Exempts ephedrine or pseudoephedrine products in liquid, liquid capsule, or dissolvable strip from the above three requirements.
- 5) Allows DOJ to adopt rules and regulations to exempt any product from these requirements if DOJ finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.
- 6) Requires DOJ to exempt, upon the application of a manufacturer of a drug product, any product DOJ determines to have been formulated in such a way as to effectively prevent the conversion of any active ingredient in the product into methamphetamine or any other controlled substance.
- 7) Provides that a violation of the provisions of this bill is a misdemeanor, and provides that a retailer or

employee of a retailer may be imprisoned for no more than one year or be fined up to ten thousand dollars (\$10,000) for a subsequent violation.

8) Prohibits a violation from being imposed in the following cases:

- a) A retail clerk shall not be guilty, not be subject to any civil penalty, or not be subject to any disciplinary action or discharge by the employer, except if the clerk is a willful participant in an ongoing criminal conspiracy to violate the law.
- b) A retailer, whose employee violates this law, shall not be guilty of a crime and not be subject to a civil penalty if the retailer complies with the storage and employee training requirements.

9) Stipulates that nothing in this bill shall alter or affect any cause of action or remedy otherwise available to a consumer under the law and that it is the Legislature's intent that this bill and Section 11100 of the Health and Safety Code shall preempt all local ordinances or regulations governing the sale by a retailer of over-the-counter products containing pseudoephedrine.

FISCAL EFFECT: According to the analysis of the Assembly

Appropriations Committee, dated May 18, 2005, would include minor nonreimbursable local costs for enforcement, permissive costs to DOJ for regulations and review of exemptions, and unknown costs to private retailers.

COMMENTS:

1. Purpose and Need for the Measure. According to the Author, AB 283 will curb crystal methamphetamine production and use in California through purchase controls on the tablet form of pseudoephedrine, a key ingredient in methamphetamine production. The costs of crystal methamphetamine production and use in California are staggering. A recent Los Angeles Times article called crystal methamphetamine "as addictive as crack, more powerful than ecstasy, and cheaper than cocaine." Despite considerable state spending and legal limits on key ingredient sales and distribution, methamphetamine use continues to increase.
2. Background. The following information has been extracted from the comments and background material



supplied by the Author.

- a) Super Labs and User Labs. Super labs are sites producing 10 pounds of methamphetamine or more in a single batch and are typically run by Mexican drug trafficking organizations. It is believed that a large percentage of methamphetamine sold in California originates from super labs both here and in Mexico. These larger operations are typically located in secluded rural locations.

Methamphetamine user labs are smaller and typically are not run by organized crime. They are difficult to find and easy to move. Methamphetamine addicts in need of a cheap source for their next fix can obtain a recipe from the internet and build a small methamphetamine lab in the trunk of a car, their bath tub, or any place out of public view. These user labs are dangerous fire and chemical hazards and pose a serious threat to public safety.

- b) Pseudoephedrine: Key Ingredient in User Lab Methamphetamine Production. The key ingredient for user lab methamphetamine production is the tablet form of ephedrine/pseudoephedrine-containing products. Current California law limits ephedrine or pseudoephedrine purchases to nine grams or three packages per transaction. Therefore, methamphetamine users, in a process they call "smurfing," travel from store to store purchasing or shop lifting these products. Law enforcement commonly reports that maps found during methamphetamine lab busts are marked with the locations of retail outlets selling such products.
- c) Methamphetamine Labs Are Accidents Waiting to Happen. Methamphetamine production requires the use of toxic solvents and when the products are cooked a flammable gas heavier than air is produced which drifts and collects at ground level. There is a considerable danger of fires and explosions. Any spark such as a neighbor's drop of a cigarette or the discharge of a police firearm can ignite an explosion that causes harm to life and property. The "off-gas" can also burn lungs and cause long-term respiratory disabilities.
- d) Methamphetamine Fueling HIV Infections. Methamphetamine use is a problem in many communities, but it is spread among middle-class gay men and is taking a high priced and deadly toll. Called crystal, tina, crank, and speed, methamphetamine is believed to

be fueling new HIV infections.

Health surveys in Los Angeles and San Francisco have found that roughly a third of the people newly diagnosed with HIV report using methamphetamine. A recent Centers for Disease Control and Prevention study of San Francisco data documented that using methamphetamine and Viagra together leads to a significant increase in unsafe sex. Another study by San Francisco's Stop AIDS Project found that 20 percent of gay and bisexual men in that city have used methamphetamine in the last 6 months. Taken together, these studies are pointing to a growing problem of methamphetamine use leading to HIV infection among men who have sex with men.

- e) User Labs Impact Children. User labs found in residential areas create fire, health, and environmental dangers to the people living nearby.

Children living and playing in buildings with methamphetamine labs inhale toxic gas that collects at floor level where adults may not detect its presence. Children also may suffer other exposure risks such as chemical burns or sticks from discarded needles. In 2003, there were 379 documented cases of California children impacted by methamphetamine labs located in their homes and neighborhoods. With thousands of undetected labs in existence, the full impact on kids and nearby residents is unknown.

- f) Environmental Concerns. For every one pound of crystal methamphetamine produced, roughly seven pounds of toxic waste is generated. Methamphetamine cooks suffering from symptomatic paranoia often feel an extreme urgency to dispose of all evidence of the lab. Toxic solvents and byproducts are dumped down drains, onto the ground, and into streams, lakes, and rivers. Buckets, coolers, and other contaminated equipment are discarded in any place where lab cooks will not be detected. Methamphetamine lab clean ups are expensive. Contaminated surfaces often cannot be cleaned and must be removed. Toxic solvent byproducts are dumped in drains damage pipes, and when dumped on the ground these solvents contaminate ground water and waterways and can kill aquatic plants and animals. Property owners may bear costs easily exceeding \$50,000 per site for everything from carpet and plumbing replacement to contaminated soil removal.

- g) AB 283 Locks Up Pseudoephedrine. In January,

Illinois implemented a new law that requires retailers to lock up the tablet form of pseudoephedrine. This law aims to reduce the shoplifting of this product by methamphetamine cooks and to prevent the accidental sale of the product by retailers to those who would use the product for the illegal manufacture of crystal methamphetamine. AB 283 in its amended form would require the training of retail employees who are specially designated to handle pseudoephedrine tablet transactions. Like Illinois law, the purpose is to help retailers understand what products may be purchased by methamphetamine cooks and to help them report suspicious pseudoephedrine purchasers to police.

- h) Restrictions to Access Will Limit Methamphetamine Production. Crystal methamphetamine users often develop feelings of paranoia that make simple tasks difficult. In Oklahoma, where a new law locked up pseudoephedrine products and required an I.D. check, law enforcement officials say the greatest deterrent effect in their new law is methamphetamine-induced paranoia; users find it impossible to go to the counter, ask for the pseudoephedrine product, show I.D., and have their identification information recorded. AB 283 will require everyone, including paranoid methamphetamine cooks, to ask a specially trained employee for the product. Irrational fear will deter many of these methamphetamine users from even trying to purchase the product.
- i) Pseudoephedrine Tablets Sold on the Internet. Most internet websites require purchasers to give their name, shipping address, and credit card information. Lots of methamphetamine cooks are too paranoid to make that transaction. States with tight controls on pseudoephedrine product sales like Oklahoma and Oregon have seen dramatic reductions in methamphetamine lab busts. Their controls would not be effective if the internet was truly a common source of pseudoephedrine for methamphetamine labs.
- j) PSE Tablets Are Instant Methamphetamine. Making methamphetamine from pseudoephedrine tablets is so easy that anyone who can measure is able to manufacture the illegal drug. Pseudoephedrine tablets are literally "instant" methamphetamine; just follow the directions on the internet.

It is true that liquid cold medicines exempted from the lock up provision of this bill can be used to make

crystal methamphetamine. However, it is far more difficult than just measuring a few ingredients.

### 3. Example of Recent Laws and Regulations of Other States.

The Georgia Legislature passed House Bill 216, which requires that all single-entity pseudoephedrine products be placed behind a counter or other barrier so that such products are not accessible by the public but only by a retail store employee or agent. The bill placed a sales restriction on all pseudoephedrine products to three packages (or nine grams), except pediatric products, and it pre-empts local ordinances. Last year the Illinois legislature passed a bill allowing retailers options in reducing consumer access to pseudoephedrine products. The law does the following: (a) limits pseudoephedrine sales to a two-package limit; (b) requires an employee of the retailer to access this product; (c) requires the product to be kept behind the counter or in a locked case; (d) requires purchaser to sign a log and show photo ID; and, (e) requires mandatory employee training.

The Oregon Board of Pharmacy recently adopted a "temporary rule" which was modeled after the Oklahoma law except that there is no requirement for the logging of each sale, no specific limitation over a 30-day period and the product is to be kept behind the counter.

### 4. Briefing Report Conducted by the Bureau of Narcotic Enforcement (BNE) of the DOJ: "Pseudoephedrine OTCs and Methamphetamine Related Issues." According to BNE's briefing report, methamphetamine and the illicit clandestine laboratories that produce it pose significant public health and safety problems in California. The social, economic, and environmental costs of methamphetamine use and production are extremely high. A large percentage of the methamphetamine consumed in the U.S. is produced right here in California. BNE indicates that California law enforcement has worked closely with the Legislature to attempt to regulate many of the chemical precursors used to produce methamphetamine. Currently, however, the most commonly used ingredient is not adequately regulated. Over the past ten years, pseudoephedrine/ephedrine has become the predominate chemical used in the production of methamphetamine. Over-the-counter pseudoephedrine-containing products are a common component used in household methamphetamine production. Last year, in at least 28% of all lab seizures in California, over-the-counter pseudoephedrine containing products were found and noted to be attributable to methamphetamine production. Although the sale of

pseudoephedrine is restricted to three packages (or nine grams) at any one time, per purchaser, it does not prevent methamphetamine users from "smurfing" the products. The BNE reviewed several states which enacted laws where controls were in place to regulate the sale of over-the-counter pseudoephedrine products and reached the conclusion that these new requirements have dramatically decreased the number of methamphetamine labs in those jurisdictions. The DOJ strongly recommended in its paper that the Legislature enact similar legislation to address the rampant clandestine methamphetamine lab problem in California.

#### 5. "Oppose Unless Amended" Issues.

- a) Exemption of gel cap and liquid type pseudoephedrine products.

Pfizer Inc. is opposed to this measure unless it is amended to include these types of pseudoephedrine products. They argue that tests conducted by law enforcement demonstrate conclusively that pseudoephedrine can be extracted from the gel cap and liquid type products by the same, commonly used criminal methods used to convert single ingredient pseudoephedrine products. In fact, they argue that law enforcement agencies have found liquid-filled capsules had some of the highest conversion rates of all products tested, and if these types of products continue to be sold over-the-counter, it is predictable these products will be used by criminals to make methamphetamine.

Pfizer also provided a letter from the Drug Enforcement Administration (DEA) of the U.S. Department of Justice regarding the use of tablets and liquid and gel-cap pseudoephedrine products. According to DEA, although gel-caps and liquids are not yet commonly found in methamphetamine labs, the chemists at DEA have run extractions on liquid and gel-cap pseudoephedrine products and found that the precursor material is readily extractable. Just recently, a lab utilizing liquids and gel-caps was seized in Oregon. While it appears that it is not yet common knowledge among lab operators that you can use these liquid or gel-cap products to make methamphetamine, this is most likely due to the notion that lab operators are creatures of habit. They follow the recipe provided or the advice of other cooks. Most of these recipes refer to tablets so this may explain why they have not seriously sought liquids or gel-caps.

DEA further indicates that their chemical control efforts have been a game of cat and mouse with clandestine lab operators. A succession of federal laws has been necessary to eliminate loopholes in the control scheme. Consequently, whenever the law has exempted a type of product or material, the traffickers have adjusted their manufacturing procedure and attempted to circumvent DEA regulations by opting for the uncontrolled source of precursor material. DEA provides as an example the exemption provided for blister pack tablets of pseudoephedrine from the reporting and recordkeeping requirements of the Controlled Substances Act. Despite warnings from DEA that utilization of blister packs would increase clandestine labs, Congress granted this exemption. Since that time, clandestine laboratory operators have increasingly exploited pseudoephedrine blister packs.

The Author states, that while there is no dispute that liquid pseudoephedrine can be used in the manufacture of meth, officials at the DOJ state that the use of liquid forms is extremely rare today and not likely to increase dramatically, at least in the short term. For one, DOJ officials note that a rise in the use of liquid pseudoephedrine has not taken place in Oklahoma or Oregon, where liquid forms were excluded from pseudoephedrine restriction laws. Second, DOJ officials state that the large volume of liquid pseudoephedrine product needed to make meth renders it unwieldy to meth cooks. The Author maintains that putting strong restrictions on solid and single-ingredient forms of pseudoephedrine and allowing the sale of liquid pseudoephedrine under less restricted conditions, targets the problem at hand while ensuring consumer access to cold medicines. The Author states that If law enforcement finds in the future that the use of liquid pseudoephedrine has risen significantly, the Legislature always has the discretion to further restrict their sales.

b) Exemptions for time-release products.

Schering-Plough, the producer of Claritin, is opposed unless this bill is amended to exempt time-release medications from the locked cabinet and retail clerk requirement, so that these medications could continue to be sold over the counter without any additional controls. Schering-Plough also contends that time-release capsules are not the primary source for making methamphetamine and that the costs of requiring these controls are not justified. At a minimum, Schering-Plough requests that there be a delay in the

implementation of this bill to enable companies to reformulate their products with a substitute for pseudoephedrine. The delay is necessary because the new products would have to go through the entire federal approval system under the Food and Drug Administration.

6. Similar Legislation This Session. SB 152 (Speier) would have required as of June 1, 2006, that a pharmacist and retail distributor, as defined, store pseudoephedrine in a locked area, required the purchaser to provide valid identification prior to purchase, and required staff of the retail distributor to be trained in identification of pseudoephedrine products and in the usage of pseudoephedrine to make methamphetamine. As of January 1, 2008, it also would have required that an electronic system be set up by a pharmacy and retail distributor to track the sale of pseudoephedrine and assure that no more than three packages or no more than 9 grams are sold within a 30-day period to a single purchaser. However, as proposed to be amended by the Author, the requirement for setting up an electronic system to track purchases would have been eliminated. Even with those amendments, SB 152 was defeated in this Committee.
7. Department of Justice (DOJ) is Neutral. DOJ is currently neutral on this bill after suggesting some amendments that have been adopted by the Author. The Department believes that this measure is definitely a step in the right direction to discourage the purchase of ephedrine/pseudoephedrine products for the purposes of manufacturing methamphetamine. However, it may not go far enough to address the entire problem. Future legislation will probably be necessary to completely respond to this situation.
8. Policy Concern. A potential concern has been raised by staff of the Public Safety Committee and DOJ in that the exemption from violation of this act by a retail clerk may be too broad. As previously noted, a retail clerk is exempt from being convicted of a crime, having to pay a civil penalty, or being disciplined or discharged, except if the retail clerk is a willful participant in an ongoing criminal conspiracy to violate the law. This would protect the retail clerk even if he or she knows that the purchaser will use the drug to make methamphetamine. In addition, this bill could effectively lower penalties for conspiracies to manufacture methamphetamine or other illegal acts by making a conspiracy to sell or provide ephedrine or pseudoephedrine in violation of a crime defined by this

bill as a misdemeanor. This bill has also been referred to the Public Safety Committee where this concern will be addressed.

NOTE : Double-referral to Public Safety Committee

#### SUPPORT AND OPPOSITION:

##### Support:

American Federation of State, County, and Municipal  
Employees (AFSCME)  
Being Alive South Bay  
California Grocers Association  
California Retailers Association  
California State Sheriff's Association  
California STD Controllers Association  
Gay and Lesbian Social Services  
Gray Panthers  
Honorable Henry Waxman, U.S. Representative, 30th District,  
California  
Internet Sexuality Information Services, Inc.  
Los Angeles County Sheriff's Department  
Pharmacists Planning Service, Inc.  
Rite Aid  
San Bernardino County, Office of the Sheriff  
San Francisco AIDS Foundation  
San Francisco City and County  
Solano County Board of Supervisors  
Stop AIDS Project  
Transgender Law Center

##### Neutral:

Department of Justice (DOJ)

##### Opposition:

Pfizer Inc (Oppose unless amended)  
Schering-Plough (Oppose unless amended)

Consultant: George Cate